

TITAN PHARMACEUTICALS INC

Form S-1

August 29, 2014

As filed with the Securities and Exchange Commission on August 29, 2014

**Registration No. 333-**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM S-1**

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**TITAN PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2836  
(Primary standard industrial  
classification code number)

94-3171940  
(I.R.S. employer  
identification number)

**400 Oyster Point Boulevard  
South San Francisco, CA 94080  
(650) 244-4990**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Sunil Bhonsle, President**  
**400 Oyster Point Boulevard**  
**South San Francisco, CA 94080**  
**(650) 244-4990**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b2 of the Exchange Act.

Large Accelerated Filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company



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Title of Each Class of Security Being Registered	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount of Registration Fee
Units, each unit consisting of: (i) one share of common stock, par value \$0.001 <sup>(3)</sup> (ii) [*] of one Class A warrant to purchase one share of common stock <sup>(3)</sup>	\$ 12,000,000	\$ 1,546
Common stock issuable upon exercise of Class A warrants included in units <sup>(4)</sup>	\$ 6,000,000	\$ 773
Underwriter's warrant <sup>(3)</sup>		
Common stock issuable upon exercise of underwriter's warrant <sup>(4)</sup>	\$ 360,000	\$ 46
Total	\$ 18,360,000	\$ 2,365

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, or the Securities Act.

(2) Pursuant to Rule 416 under the Securities Act, there are also being registered such additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(3) No separate fee is required pursuant to Rule 457(g) under the Securities Act.

(4) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS**

**SUBJECT TO COMPLETION, AUGUST 29, 2014**

**TITAN PHARMACEUTICALS, INC.**

**[\*] Units**

**Each Unit Consisting of One Share of Common Stock  
and**

**[\*] of a Class A Warrant, Each to Purchase One Share  
of Common Stock**

We are offering [\*] units, each of which consists of one share of our common stock and [\*] of a Class A Warrant, each to purchase one share of our common stock at an exercise price of [\*] per share. The Class A Warrants will be immediately exercisable and will expire on the [\*] anniversary of the issuance date. No units will be issued, however, and purchasers will receive only shares of common stock and Class A Warrants. The common stock and the Class A Warrants may be transferred separately immediately upon issuance.

Our common stock is quoted on the OTCBB under the symbol TTNP. On [\*], 2014, the closing price of our common stock as quoted on the OTCBB was \$[\*]. We do not intend to list the Class A Warrants on any securities exchange or other trading market and we do not expect that a public trading market will develop for the Class A Warrants. Without an active market, the liquidity of the Class A Warrants will be limited.

**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 4 of this prospectus.**

	Per Unit	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us, before expenses <sup>(2)</sup>	\$	\$

(1) The underwriter will receive compensation in addition to the underwriting discount. See Underwriting beginning on page 49 of this prospectus for a description of compensation payable to the underwriter.

(2) We estimate the total expenses of this offering, excluding the underwriting discount, will be approximately \$ . In addition to the discounts and commissions listed above, we have agreed to issue to the underwriter or its designees underwriter s warrants to purchase shares of common stock equal to 3% of the total number of shares included in the units. The underwriter s warrants will have the same terms, including the exercise price, as the warrants issued to investors, except that the underwriter s warrants will comply with FINRA Rule 5110(g)(1). The registration statement of which this prospectus is a part also covers the underwriter s warrants and the shares of common stock issuable upon

[\*] Units Each Unit Consisting of One Share of Common Stock and [\*] of a Class A Warrant, Each to Purchase One

the exercise thereof. We have also agreed to reimburse the underwriter for certain of its reasonable out-of-pocket expenses up to \$75,000. See Underwriting beginning on page 49 for more information on this offering and the underwriting arrangements. All costs associated with the registration will be borne by us.

The underwriter expects to deliver the units against payment on or about [\*], 2014.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**Roth Capital Partners**

The date of this prospectus is \_\_\_\_\_, 2014

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You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf. We have not, and the underwriter has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriter is not, making an offer to sell these securities in any jurisdiction where the offer is not permitted.

The information contained in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any authorized free writing prospectus or the time of issuance or sale of any securities. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus and any free writing prospectus that we have authorized for use in connection with this offering in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the section of this prospectus entitled "Where You Can Find More Information."

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## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act.

Forward-looking statements reflect the current view about future events. When used in this prospectus, the words anticipate, believe, estimate, expect, future, intend, plan, or the negative of these terms and similar expressions they relate to us or our management, identify forward-looking statements. Such statements, include, but are not limited to, statements contained in this prospectus relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, the results of clinical trials and the regulatory approval process; our ability to raise capital to fund continuing operations; market acceptance of any products that may be approved for commercialization; our ability to protect our intellectual property rights; the impact of any infringement actions or other litigation brought against us; competition from other providers and products; our ability to develop and commercialize new and improved products and services; changes in government regulation; our ability to complete capital raising transactions; and other factors (including the risks contained in the section of this prospectus entitled Risk Factors ) relating to our industry, our operations and results of operations. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.



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## PROSPECTUS SUMMARY

*This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read the entire prospectus carefully. References herein to we, us, Titan, and our company refer to Titan Pharmaceuticals, Inc. and its subsidiaries unless the context otherwise requires.*

### The Company

We are a specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit.

Probuphine®, our first product candidate to utilize ProNeura, is in development for the long term maintenance treatment of opioid dependence designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. We have licensed the U.S. and Canadian rights to Probuphine to Braeburn Pharmaceuticals Sprl ( Braeburn ). In April 2013, the FDA issued a Complete Response Letter ( CRL ) to the New Drug Application ( NDA ) we submitted the prior year stating that it cannot approve the NDA in its present form and outlining the FDA s request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program for insertion and removal of the implants, as well as recommendations regarding product labeling, Risk Evaluation and Mitigation Strategy ( REMS ) and non-clinical safety data.

Since receipt of the CRL we have been working with Braeburn, a team of expert clinical and regulatory advisors and the FDA to establish a path forward for Probuphine, which along with other steps includes conducting an additional clinical study in clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patient enrollment in this 180 patient clinical study, which is being funded and managed by Braeburn, began in July 2014 and study completion is anticipated by the middle of 2015 followed by resubmission of the NDA later in the year. Pursuant to our license agreement with Braeburn, as amended to date, we are entitled to receive a \$15 million milestone payment upon FDA approval of the Probuphine NDA and percentage royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. The agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones and entitles us to royalty rates in the low single digit on sales by Braeburn, if any, of other future products in the addiction market.

We believe that our ProNeura technology has the potential to be used in the treatment of other chronic conditions, such as Parkinson s disease (PD), where maintaining stable, around the clock blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. We have commenced initial work on an implant formulation with ropinirole, a dopamine agonist approved for the treatment of PD, and intend to use a portion of the proceeds of this offering to advance this program, including the development of a proof of concept clinical study. We are also currently evaluating drugs and disease settings for opportunities to develop our drug delivery technology for other potential treatment applications in situations where conventional treatment is limited by variability in blood drug levels and poor patient compliance and where existing therapeutic compounds have sufficient potency to be effective at low doses.

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Our principal executive offices are located 400 Oyster Point Boulevard, Suite 505 South San Francisco, CA 94080.  
Our telephone number is (650) 238-6621.

Probuphine® and ProNeura™ are trademarks of Titan Pharmaceuticals, Inc. This prospectus also includes trade names and trademarks of companies other than Titan Pharmaceuticals, Inc.

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## The Offering

### Securities we are offering

[\*] units (assuming an offering price of \$[\*] per unit, the closing price of our common stock on [ ], 2014), each consisting of one share of our common stock and [\*] of a Class A Warrant, each to purchase one share of our common stock at an exercise price of \$[\*] per share. The Class A Warrants will be immediately exercisable and will expire on the [\*] anniversary of the issuance date.

### Public offering price

\$[\*] per unit

### Common stock outstanding before this offering<sup>(1)</sup>

[\*] shares

### Common stock to be outstanding after the offering<sup>(2)</sup>

[\*] shares or [\*] shares if the Class A Warrants sold in this offering are exercised in full.

### Use of proceeds

We intend to use the net proceeds of this offering to support ongoing Probuphine development and ex-U.S. partnering efforts, for pre-clinical development of other ProNeura technology-based products and for working capital and other general corporate purposes.

### Risk factors

See Risk Factors beginning on page 4 for a discussion of risks you should consider before purchasing shares of our common stock.

### Market symbol and listing

Our common stock is currently quoted on the OTCQB under the symbol TTNP . We do not intend to list the Class A Warrants on any securities exchange or other trading market and we do not expect that a public trading market will develop for the Class A Warrants. Without an active market, the liquidity of the Class A Warrants will be limited.

The number of shares of our common stock prior to and to be outstanding immediately after this offering as set forth in the table above is based on 88,997,533 shares of our common stock outstanding as of August 25, 2014. The number of shares outstanding as of August 25, 2014 excludes, as of that date:

6,670,053 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$1.25;

5,450,892 shares issuable upon exercise of outstanding warrants with an exercise price of \$1.16;

358,400 shares subject to vested restricted stock awards;

shares of common stock issuable upon the exercise of the Class A Warrants offered hereby; and

shares of common stock issuable upon the exercise of the underwriter's warrants.

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## **RISK FACTORS**

*This investment has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties described below and the other information in this prospectus. If any of the following risks actually occur, our business, operating results and financial condition could be harmed and the value of our stock could go down. This means you could lose all or a part of your investment.*

### **Risks Associated with our Business**

#### **Further delays in the FDA approval process for Probuphine or termination of the license agreement by Braeburn could materially adversely impact our liquidity and financial condition.**

While Braeburn has commenced the clinical study and patient enrollment is underway, we cannot predict the timing of commencement or completion of the study. At June 30, 2014, we had cash of approximately \$8.9 million, which we believe is sufficient to fund our planned operations into June 2015. Under our license agreement, as amended, Braeburn currently has the technical right to terminate the agreement. If Braeburn were to exercise this right, we would not have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine without raising additional capital. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted. We cannot assure you that the financing we need will be available on acceptable terms.

#### **FDA approval of Probuphine may be denied.**

While Titan and Braeburn have agreed in principal with the FDA on a path forward for Probuphine, which along with other steps includes conducting an additional clinical study for which patient enrollment has commenced, there can be no assurance that the FDA will ultimately approve the NDA. The FDA may deny approval of Probuphine for many reasons, including:

we may be unable to demonstrate to the satisfaction of the FDA that Probuphine is safe and effective for the treatment of opioid dependence in the targeted patient population;

the FDA may disagree with our interpretation of data from the clinical trial;

we may be unable to demonstrate that Probuphine's clinical and other benefits outweigh any safety or other perceived risks; or

we may not be able to successfully address the other issues raised by the FDA in the CRL.

If Probuphine fails to receive FDA approval, our business and prospects will be materially adversely impacted.

#### **Even if we obtain FDA approval of Probuphine, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.**

In order to market Probuphine outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that

regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

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**The timing and amount of revenues from Probuphine, if any, will be wholly dependent on the efforts of third parties.**

We have granted an exclusive license to Braeburn for the commercialization of Probuphine in the United States and Canada (the Territory). If approved by the FDA, Braeburn will be solely responsible for the marketing, manufacture and commercialization of Probuphine in the Territory and, accordingly, the timing and amount of any royalty revenues or sales milestones we receive from this product will be wholly dependent upon Braeburn's ability to successfully launch and commercialize this product in the Territory. Braeburn is a recently formed company and does not have a track record upon which investors can rely on making an investment decision. Additionally, our ability to generate revenues in the Territory from any additional indications for Probuphine, including chronic pain, depends on Braeburn's ability to successfully develop, obtain regulatory approvals for and commercialize the product for additional indications. We do not have control over the amount and timing of resources that Braeburn will dedicate to these efforts, none of which have commenced to date. We will be similarly dependent on the development, regulatory and marketing efforts of third parties with respect to revenues, if any, from sales of Probuphine outside the Territory. To date, we have not entered into any collaborative arrangements or granted any rights with respect to Probuphine in the rest of the world.

**Our ProNeura development programs are at very early stages and will require substantial additional resources that may not be available to us.**

To date, we have conducted limited research and development activities based on our ProNeura delivery system beyond Probuphine. We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization of ProNeura for PD or any therapeutic based on our ProNeura platform technology. If we are unable to generate sufficient revenues from royalties from the sale of Probuphine or other payments under our license agreement with Braeburn, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in raising the requisite financing on acceptable terms, we may be unable to initiate clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts and forego attractive business opportunities.

To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our shareholders. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

**Our ProNeura program for PD is at a very early stage and we may not be able to successfully develop this product or any other product based on our ProNeura drug delivery technology.**

The timing and amount of revenues from Probuphine, if any, will be wholly dependent on the efforts of third parties.

Our ability to successfully develop any future product candidates based on our ProNeura drug delivery technology is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on its own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance.

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successful, our business, financial condition, and results of operations may be materially harmed.

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**Our development and commercialization strategy for ProNeura for PD depends, in part, upon the FDA's prior findings regarding the safety and efficacy of ropinirole based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.**

We are developing ProNeura for PD with the expectation that it will be eligible for approval through the regulatory pathway under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA allows an NDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product, which could expedite the development program for ProNeura for PD by potentially decreasing the amount of clinical data that would need to be generated in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for ProNeura for PD, and complications and risks associated with regulatory approval, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than ProNeura for PD, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that this regulatory pathway will ultimately lead to accelerated product development or earlier approval for ProNeura for PD. Moreover, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this result could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of ProNeura for PD. The FDA may require us to perform additional studies or measurements to support any changes in our product as compared to the approved product. If we utilize Section 505(b)(2), the FDA may approve our new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by us.

**Clinical trials required for new product candidates are expensive and time-consuming, and their outcome is uncertain.**

In order to obtain FDA approval to market a new drug product based on our ProNeura drug delivery technology, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct adequate and well controlled clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of qualified materials under cGMP, for use in clinical trials; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients; modification of clinical trial protocols; changes in regulatory requirements for clinical trials; the lack of effectiveness during clinical trials; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and government or regulatory delays or clinical holds requiring suspension or termination of the trials.



The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials.

Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operation.

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**If Probuphine or any other product candidate that we may successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.**

Even if Probuphine or any other product candidate we may in the future develop receives regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective product;
- the potential and perceived advantages of the product over alternative treatments;
- the safety of the product in broader patient groups, including its use outside of approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- the prevalence and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals and clinics, healthcare payors and patients, we may not generate significant revenue from such products.

**We must comply with extensive government regulations.**

The research, development, manufacture labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of pharmaceutical products are subject to an extensive regulatory approval process by the FDA in the U.S. and comparable health authorities in foreign markets. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Approval policies or regulations may change and the FDA and foreign authorities have substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Regulatory approval may entail limitations on the indicated usage of a drug, which may reduce the drug's market potential. Even if regulatory clearance is obtained, post-market evaluation of the products, if required, could result in restrictions on a product's marketing or withdrawal of the product from the market, as well as possible civil and criminal sanctions. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized.

**We are dependent upon key collaborative relationships and license agreements.**

We will rely significantly on the resources of third parties to market and commercialize Probuphine, if approved, as well as any other products we may develop. For example, our ability to ultimately derive revenues from Probuphine in the United States and Canada is dependent upon Braeburn implementing a successful marketing program for the treatment of opioid dependence in adults and pursuing development and commercialization of the product for other

If Probuphine or any other product candidate that we may successfully develop does not achieve broad market acco

indications. Beyond any contractual rights, we cannot control the amount or timing of resources that any existing or future corporate partner devotes to product development and commercialization efforts for our product candidates. We depend on our ability to maintain existing collaborative relationships, to develop new collaborative relationships with third parties and potentially to acquire or in-license additional products and technologies for the development of new product candidates.

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Our dependence on third party collaborators and license agreements subjects us to a number of risks, including:

our collaborators may not comply with applicable regulatory guidelines with respect to developing or commercializing our products, which could adversely impact sales or future development of our products; we and our collaborators could disagree as to future development plans and our collaborators may delay, fail to commence or stop future clinical trials or other development; and

there may be disputes between us and our collaborators, including disagreements regarding the license agreements, that may result in the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments and/or the delay or termination of any future development or commercialization of our products.

In addition, collaborators may, to the extent permitted by our agreements, develop products that divert resources from our products, preclude us from entering into collaborations with their competitors or terminate their agreements with us prematurely. Moreover, disagreements could arise with our collaborators or strategic partners over rights to our intellectual property and our rights to share in any of the future revenues from products or technologies resulting from use of our technologies, or our activities in separate fields may conflict with other business plans of our collaborators.

**We face risks associated with third parties conducting preclinical studies and clinical trials of our products; as well as our dependence on third parties to manufacture any products that we may successfully develop.**

We depend on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We also depend upon third party manufacturers for the production of any products we may successfully develop to comply with current Good Manufacturing Practices of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated. Similarly, if the manufacturers of any products we develop in the future fail to comply with current Good Manufacturing Practices of the FDA, we may be forced to cease manufacturing such product until we have found another third party to manufacture the product.

**We face risks associated with product liability lawsuits that could be brought against us.**

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims. We currently have a limited amount of product liability insurance, which may not be sufficient to cover claims that may be made against us in the event that the use or misuse of our product candidates causes, or merely appears to have caused, personal injury or death. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. Adequate insurance coverage may not be available in the future on acceptable terms, if at all. If available, we may not be able to maintain any such insurance at sufficient levels of coverage and any such insurance may not provide adequate protection against potential liabilities.

Whether or not a product liability insurance policy is obtained or maintained in the future, any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim.

We face risks associated with third parties conducting preclinical studies and clinical trials of our products as well as

**We may be unable to protect our patents and proprietary rights.**

Our future success will depend to a significant extent on our ability to:

obtain and keep patent protection for our products and technologies on an international basis;  
enforce our patents to prevent others from using our inventions;  
maintain and prevent others from using our trade secrets; and  
operate and commercialize products without infringing on the patents or proprietary rights of others.

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We cannot assure you that our patent rights will afford any competitive advantages, and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the U.S. or abroad. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent. If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

In addition, third parties may sue us for infringing their patents. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop using our technologies and methods;
- stop certain research and development efforts;
- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others.

Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor.

### **We face intense competition.**

Competition in the pharmaceutical and biotechnology industries is intense. We face, and will continue to face, competition from numerous companies that currently market, or are developing, products for the treatment of the diseases and disorders we have targeted. Many of these entities have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization or patent protection earlier than we will.

### **Healthcare reform and restrictions on reimbursements may limit our financial returns.**

Braeburn's ability to commercialize Probuphine in the Territory and our ability or the ability of any future collaborators to commercialize Probuphine outside the Territory or to commercialize any other products we may

successfully develop will depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our own or our collaborator's drug products to

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enable us or them to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

**Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products.**

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If our products are not widely included on the formularies of these plans, our ability to market our products may be adversely affected.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (jointly, the PPACA ), which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any transfer of value made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required and reporting to the Centers for Medicare & Medicaid Services (the CMS ) required by the 90<sup>th</sup> day of each calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;





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a licensure framework for follow-on biologic products;  
a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;  
creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and  
establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA ), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.



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**We may not be able to retain our key management and scientific personnel, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.**

As a company with a limited number of personnel, we are highly dependent on the services of our executive management and scientific staff, in particular Sunil Bhonsle and Marc Rubin, our President and Executive Chairman, respectively, and Katherine Glassman-Beebe our Executive Vice President and Chief Development Officer. The loss of one or more of such individuals could substantially impair ongoing research and development programs and could hinder our ability to obtain corporate partners. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may not be successful in our efforts to attract and retain personnel.

**Our net operating losses and research and development tax credits may not be available to reduce future federal and state income tax payments.**

At December 31, 2013, we had federal net operating loss and tax credit carryforwards of \$225.6 million and \$8.2 million, respectively, and state net operating loss and tax credit carryforwards of \$157.7 million and \$8.0 million, respectively, available to offset future taxable income, if any. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change and we cannot assure you that our net operating loss and tax carryforwards will continue to be available.

**Risks Associated with our Capital Stock**

**Following this offering, we will have a limited number of authorized shares of common stock available for issuance and will need to seek stockholder approval to amend our charter to either effect a reverse stock split or an increase in our authorized shares.**

Immediately following this offering, we will have only [\*] authorized but unissued shares of our common stock. We will need to continue to seek additional financing in order to fund our product development programs until such time, if ever, as the Probuphine NDA is approved by the FDA and royalty and milestone payments are sufficient to fund our operations. We intend to seek stockholder approval of an amendment to our certificate of incorporation to either effect a reverse stock split, thereby making additional shares available for issuance, or increase the number of authorized shares of common stock. There are risks associated with effecting a reverse split, including a decline in the market price of our common stock and the possibility of certain shareholders owning odd lots of less than 100 shares, which may be more difficult to sell, or require greater transaction costs per share to sell, than shares in round lots of even multiples of 100 shares. In addition, because holders of our common stock have no preemptive rights to purchase or subscribe for any unissued stock of our company, the availability of a greater number of authorized shares, whether as a result of a reverse split or an increase in the authorized number, could result in additional dilution to existing shareholders and investors in this offering.

**Our stock price has been and will likely continue to be volatile.**

Our stock price has experienced substantial fluctuations and could continue to fluctuate significantly due to a number of factors, including:

variations in our anticipated or actual operating results or prospects;  
sales of substantial amounts of our common stock;  
announcements about us or about our competitors, including introductions of new products;  
litigation and other developments relating to our patents or other proprietary rights or those of our competitors;  
conditions in the pharmaceutical or biotechnology industries;  
governmental regulation and legislation; and  
change in securities analysts estimates of our performance, or our failure to meet analysts expectations.

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**Our common stock is not listed on a national securities exchange and we may not be able to obtain an uplisting to a national exchange in the foreseeable future, if ever.**

Our common stock is currently listed on the OTCBB. Trading on the OTC Market is characterized by wide fluctuations in bid and asked prices and periods of inactive or limited trading. We expect to commence efforts to seek an uplisting to the Nasdaq Stock Market or another national securities exchange following completion of this offering; however, we do not know whether we will be able to meet the initial listing criteria to enable us to obtain an uplisting of our common stock in the foreseeable future, if ever.

**Our common stock is deemed to be a penny stock, which may make it more difficult for investors to sell their shares due to suitability requirements.**

Our common stock is subject to Rule 15g-1 through 15g-9 under the Securities Exchange Act of 1934, as amended (the Exchange Act), which imposes certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and accredited investors (generally, individuals with a net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000 (or \$300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares of common stock.

Additionally, our common stock is subject to the SEC regulations for penny stock. Penny stock includes any equity security that is not listed on a national exchange and has a market price of less than \$5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

**We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.**

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.**

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management,

Our common stock is not listed on a national securities exchange and we may not be able to obtain an uplisting to a

including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

the inability of stockholders to call special meetings; and  
the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors.

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In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

## **Risks Associated with the Offering**

### **Our management will have broad discretion in the use of the net proceeds of this offering and may not use them effectively.**

We intend to use the net proceeds from this offering for general corporate purposes and to continue non-clinical and clinical development of our product candidates. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

### **You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.**

Because the public offering price per share of our common stock is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to assumed sale of [\*] units in this offering at an assumed public offering price of \$[\*] per unit (the closing price of our common stock on , 2014), and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and attributing no value to the Class A Warrants, if you purchase units in this offering, you will suffer immediate and substantial dilution of approximately \$[\*] per share in the net tangible book value of the common stock you acquire. In the event that you exercise your Class A Warrants, you will experience additional dilution to the extent that the exercise price of those warrants is higher than the book value per share of our common stock. See Dilution below for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

### **The exercise of outstanding options and warrants to acquire shares of our common stock would cause additional dilution which could cause the price of our common stock to decline.**

In the past, we have issued options and warrants to acquire shares of our common stock. At August 25, 2014, there were 5,450,892 warrants, and 6,594,726 vested and 75,327 non-vested stock options outstanding, and we may issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these



options and warrants are ultimately exercised, existing holders of our common stock would experience additional dilution which may cause the price of our common stock to decline.

**There is no public market for the Class A Warrants being sold in this offering.**

There is no established public trading market for the Class A Warrants being offered in this offering, and we do not expect a market to develop. We do not intend to apply for listing of the Class A Warrants on any securities exchange or other trading market. Without an active market, the liquidity of the Class A Warrants will be limited.

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**Because our common stock is not listed on a national securities exchange, U.S. holders of warrants may not be able to exercise their warrants without compliance with applicable state securities laws and the value of your warrants may be significantly reduced.**

Because our common stock is not listed on a national securities exchange, the exercise of the warrants by U.S. holders may not be exempt from state securities laws. As a result, depending on the state of residence of a holder of the warrants, a U.S. holder may not be able to exercise its warrants unless we comply with any state securities law requirements necessary to permit such exercise or an exemption applies. Although we plan to use our reasonable efforts to assure that U.S. holders will be able to exercise their warrants under applicable state securities laws if no exemption exists, there is no assurance that we will be able to do so. As a result, your ability to exercise your warrants may be limited. The value of the warrants may be significantly reduced if U.S. holders are not able to exercise their warrants under applicable state securities laws.

**Holders of our Class A Warrants will have no rights as a common stockholder until they acquire our common stock.**

Until you acquire shares of our common stock upon exercise of your Class A Warrants, you will have no rights with respect to our common stock. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

**A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock.**

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may decline to a market price at which buyers are willing to purchase the offered shares of common stock and sellers remain willing to sell the shares. All of the securities issued in the offering will be freely tradable without restriction or further registration under the Securities Act.

**The Class A warrants may not have any value.**

The Class A warrants have an exercise price of \$[\*] per share and expire on the [\*] anniversary of the initial date of issuance. In the event our common stock price does not exceed the exercise price of the Class A warrants during the period when the Class A warrants are exercisable, the Class A warrants may not have any value.

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## MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our common stock is traded in the over-the-counter market and has been quoted through the Over-The-Counter Bulletin Board under the symbol TTNP since June 2010. The following table sets forth, for the periods indicated, the high and low sale prices for our common stock as reported by the OTCBB. Quotations on the OTCBB reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

	High	Low
Fiscal 2014		
Third Quarter (through August 25, 2014)	\$ 0.87	\$ 0.55
Second Quarter	\$ 0.86	\$ 0.55
First Quarter	\$ 0.84	\$ 0.60
Fiscal 2013		
Fourth Quarter	\$ 1.17	\$ 0.58
Third Quarter	\$ 0.70	\$ 0.46
Second Quarter	\$ 1.95	\$ 0.43
First Quarter	\$ 2.48	\$ 1.19
Fiscal 2012		
Fourth Quarter	\$ 1.23	\$ 0.76
Third Quarter	\$ 1.05	\$ 0.65
Second Quarter	\$ 1.13	\$ 0.65
First Quarter	\$ 1.40	\$ 1.05

### Holders

At August 25, 2014, there were 88,997,533 shares of our common stock outstanding held by 143 holders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

### Dividends

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends to shareholders in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as the Board of Directors deem relevant.

### Equity Compensation Plan Information

The following table sets forth aggregate information regarding our equity compensation plans in effect as of December 31, 2013:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrant and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (c)
Equity compensation plans approved by security holders	4,170,153	\$ 1.31	
Equity compensation plans not approved by security holders <sup>(1)(2)(3)</sup>	2,562,000	\$ 1.32	
Total	6,732,153	\$ 1.31	

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(1) In August 2002, we amended our 2001 Employee Non-Qualified Stock Option Plan. Pursuant to this amendment, a total of 1,750,000 shares of common stock were reserved and authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. At December 31, 2013, 1,199,500 of these non-qualified stock options remained outstanding.

(2) In October 2007, we granted 1,500,000 non-qualified stock options outside of our stock option plans to our Chief Executive Officer, at an exercise price of \$2.40, vesting equally over 48 months from the date of grant. At December 31, 2013, 437,500 of these non-qualified stock options remained outstanding.

(3) In May 2009, we granted 615,000 and 310,000 non-qualified stock options outside of our stock option plans to our Executive Chairman and President, respectively, at an exercise price of \$0.79, vesting equally over 48 months from the date of grant.

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## **USE OF PROCEEDS**

We estimate that the net proceeds from the sale of the units we are offering will be approximately \$[\*], assuming the sale by us of all of the [\*] units offered hereby at an assumed public offering price of \$[\*] per unit (the closing price of our common stock on [\*], 2014) after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount does not include any proceeds we may receive upon the exercise of any

Class A Warrants. We cannot predict when or if the Class A Warrants will be exercised, and it is possible that the Class A Warrants may expire and never be exercised.

A \$[\*] increase (decrease) in the assumed offering price of \$[\*] per unit would increase (decrease) the expected net cash proceeds of the offering to us by approximately \$[\*]. A [\*] increase (decrease) in the assumed number of units sold in this offering would increase (decrease) the expected net cash proceeds of the offering to us by approximately \$[\*], assuming a public offering price of \$[\*] per unit.

We intend to use the proceeds of this offering to support Probuphine development and ex-U.S. partnering efforts, to advance the ProNeura for PD product development program, to evaluate other ProNeura technology based product opportunities and for working capital and other general corporate purposes.

Until we use the net proceeds of the offering, we will invest the funds in short-term, investment grade, interest-bearing securities, or in savings accounts.

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If you purchase any of the units offered by this prospectus, you will experience dilution to the extent of the difference between the offering price per unit you pay in this offering and the net tangible book value per share of our common stock immediately after this offering, assuming no value is attributed to the Class A Warrants included in the units. Our net tangible book value as of June 30, 2014 was \$3,463, or approximately \$0.00 per share of common stock. Net tangible book value per share is equal to our total tangible assets minus total liabilities, divided by the number of shares of common stock outstanding.

After giving effect to the assumed sale by us of [\*] units in this offering at an assumed public offering price of \$[\*] per unit (the closing price of our common stock on [\*, 2014), assuming no value is attributed to the Class A Warrants included in the units, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2014 would have been approximately \$[\*], or approximately \$[\*] per share of common stock. This represents an immediate increase in net tangible book value of approximately \$[\*] per share to existing stockholders and an immediate dilution of approximately \$[\*] per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per unit	\$
Net tangible book value per share as of June 30, 2014	\$ 0.00
Increase per share attributable to new investors	
As adjusted net tangible book value per share after this offering	
Dilution per share to new investors	\$

Investors that acquire additional shares of common stock through the exercise of the Class A Warrants offered hereby may experience additional dilution depending on our net tangible book value at the time of exercise.

A \$[\*] increase (decrease) in the assumed public offering price of \$[\*] per unit would increase (decrease) our as adjusted net tangible book value by approximately \$[\*] and dilution per share to new investors by approximately \$[\*], assuming that the number of units offered by us, remains the same. A [\*] increase (decrease) in the number of units offered by us would increase (decrease) our as adjusted net tangible book value per share by approximately \$[\*] and dilution per share to new investors by approximately \$[\*], assuming a public offering price of \$[\*] per unit.

The number of shares of our common stock reflected in the discussion and the table above is based on 88,997,533 shares of our common stock outstanding as of June 30, 2014 and excludes, as of that date:

6,670,053 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$1.25;  
 5,450,892 shares issuable upon exercise of outstanding warrants with an exercise price of \$1.16;  
 358,500 shares subject to unvested restricted stock awards;  
 shares of common stock issuable upon the exercise of the Class A Warrants offered hereby; and  
 shares of common stock issuable upon the exercise of the underwriter's warrants.





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# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read this discussion together with the consolidated financial statements and other consolidated financial information included in this prospectus.*

## Overview

We are a specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit.

Our principal asset is Probuphine®, our first product candidate to utilize ProNeura. Probuphine is in development for the long term maintenance treatment of opioid dependence. It is designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. Upon completion of the Phase 3 clinical studies of Probuphine, we participated in a pre-NDA meeting with the FDA, and subsequently prepared and submitted the New Drug Application to the FDA in October 2012. On April 30, 2013, the FDA issued a complete response letter to our NDA stating that it cannot approve the NDA in its present form and outlining the FDA's request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program for insertion and removal of the implants, as well as recommendations regarding product labeling, Risk Evaluation and Mitigation Strategy (REMS) and non-clinical safety data.

Our efforts since receipt of the CRL have focused on working with Braeburn, a team of expert clinical and regulatory advisors and the FDA to establish a path forward for potential resubmission of the NDA with the additional information requested by the FDA. Following a meeting with the FDA on November 19, 2013 and subsequent communications, the FDA has provided guidance on a path forward, which along with other steps includes conducting an additional clinical study. This study, which is being funded and managed by Braeburn, is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms.

The study population is clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients will be randomized to receive either four Probuphine implants, or to continue the daily sublingual buprenorphine therapy. The patients are expected to be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms. Patient enrollment in this 180 patient clinical study began in July 2014 and study completion is anticipated by the middle of 2015 followed by resubmission of the NDA later in the year.

Pursuant to the license agreement with Braeburn, as amended to date, we are entitled to receive a \$15 million milestone payment upon FDA approval of the Probuphine NDA and royalty percentages on net sales of Probuphine ranging from the mid-teens to the low twenties. The agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones and entitles us to royalty rates in the low single digit on sales by Braeburn, if any, of other future products in the addiction market.

Probuphine is the first product candidate to utilize ProNeura, our novel, proprietary, continuous drug delivery technology. We believe that our ProNeura technology has the potential to be used in the treatment of other chronic

conditions, such as Parkinson's disease (PD), where maintaining stable, around the clock blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. We have commenced initial work on an implant formulation with ropinirole, a dopamine agonist approved for the treatment of PD. We are also currently evaluating drugs and disease settings for opportunities to develop this drug delivery technology for other potential treatment applications in situations where conventional treatment is limited by variability in blood drug levels and poor patient compliance. We operate in only one business segment, the development of pharmaceutical products.

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## **Critical Accounting Policies and Use of Estimates**

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. We believe the following accounting policies for the years ended December 31, 2013 and 2012 to be applicable:

### **Revenue Recognition**

We generate revenue principally from royalty payments, collaborative research and development arrangements, technology licenses, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt™ by Novartis in the U.S. As described in Note 4 to our financial statements, Agreement with Sanofi-Aventis SA and Note 8 to our financial statements, Royalty Liability, we are obligated to pay royalties on such sales to Sanofi-Aventis and Deerfield. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our Statement of Operations.

Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. Payments received related to substantive, performance-based at-risk milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.

Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.

## Share-Based Payments

We recognize compensation expense for all share-based awards made to employees and directors. The fair value of share-based awards is estimated at the grant date based on the fair value of the award and is recognized as expense, net of estimated pre-vesting forfeitures, ratably over the vesting period of the award.

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We use the Black-Scholes option pricing model to estimate the fair value method of our awards. Calculating stock-based compensation expense requires the input of highly subjective assumptions, including the expected term of the share-based awards, stock price volatility, and pre-vesting forfeitures. We estimate the expected term of stock options granted for the years ended December 31, 2013 and 2012 based on the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and the expectations of future employee behavior. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock. The assumptions used in calculating the fair value of stock-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected pre-vesting forfeiture rate and only recognize expense for those shares expected to vest. We estimate the pre-vesting forfeiture rate based on historical experience. If our actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

### **Income Taxes**

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable.

### **Clinical Trial Accruals**

We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations ( CROs ) and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. The actual clinical trial costs for the Probuphine studies conducted in the past three years have not differed materially from the estimated projection of expenses.

### **Warrants Issued in Connection with Equity Financing**

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle warrants in cash. For warrants issued with deemed possibility of

cash settlement, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as a non-cash gain or loss in the Statements of Operations and Comprehensive Income (Loss).

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## Results of Operations

### Six Months Ended June 30, 2014 Compared to Six Months Ended June 30, 2013

License revenues of approximately \$1.8 million and \$5.9 million for the six months ended June 30, 2014 and 2013, respectively, reflect the amortization of the upfront license fee received from Braeburn in December 2012. We recognized no net royalty revenues during the six month ended June 30, 2014 compared to \$1.4 million during the six months ended June 30, 2013 reflecting royalties paid on sales of Fanapt, all of which were paid to Deerfield in accordance with our royalty sales agreement. Beginning April 2013, we no longer recognize Fanapt royalty revenues since all of such royalties are paid to third parties.

Research and development expenses for the three month period ended June 30, 2014 were approximately \$0.7 million, compared to approximately \$1.8 million for the comparable period in 2013, a decrease of approximately \$1.1 million, or 61%. Research and development expenses for the six month period ended June 30, 2014 were approximately \$1.7 million, compared to approximately \$5.7 million for the comparable period in 2013, a decrease of approximately \$4.0 million, or 70%. The decrease in research and development costs was primarily associated with a decrease in external research and development expenses related to completion of the product development program and preparation and review of the NDA for our Probuphine product with the FDA. During the three and six month periods ended June 30, 2014, external research and development expenses relating to our Probuphine product development program were approximately \$36,000 and \$146,000, respectively. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this prospectus, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. However, we anticipate that our research and development expenses will increase in connection with our ProNeura for PD development activities and any other ProNeura technology based product development program we may pursue.

General and administrative expenses for the three month periods ended June 30, 2014 and 2013 were approximately \$0.7 million. General and administrative expenses for the six month period ended June 30, 2014 were approximately \$1.6 million, compared to approximately \$1.8 million for the comparable period in 2013, a decrease of approximately \$0.2 million, or 11%. The decrease in general and administrative expenses during the six month period ended June 30, 2014 was primarily related to decreases in non-cash stock compensation and employee related costs of approximately \$53,000 and legal fees of approximately \$0.2 million. This was offset in part by increases in depreciation of approximately \$58,000.

Net other expense for the three month period ended June 30, 2014 was approximately \$0.3 million which was primarily related to non-cash losses on changes in the fair value of warrants compared to net other income of approximately \$5.4 million in the comparable period in 2013 which was primarily related to non-cash gains on changes in the fair value of warrants. Net other expense for the six month period ended June 30, 2014 was approximately \$1.2 million which was primarily related to non-cash losses on changes in the fair value of warrants. Net other income during the comparable period in 2013 was approximately \$11.2 million, consisting primarily of approximately \$9.0 million in other income generated by the termination of Titan's royalty repurchase agreement with Deerfield, an approximately \$1.9 million gain resulting from the settlement of indebtedness to Deerfield as a result of the exercise of all of the Deerfield Warrants and non-cash gains on changes in the fair value of warrants of approximately \$2.3 million, which amounts were offset in part by interest expense of approximately \$1.6 million

related to the Deerfield loans and approximately \$0.5 million in other expenses related to unamortized transaction fees related to the initial Deerfield debt transaction.

Our net loss for the three month period ended June 30, 2014 was approximately \$0.8 million, or approximately \$0.01 per share, compared to our net income of approximately \$5.1 million, or approximately \$0.06 per share, for the comparable period in 2013. Our net loss for the six month period ended June 30, 2014 was approximately \$2.6 million, or approximately \$0.03 per share, compared to our net income of approximately \$11.1 million, or approximately \$0.14 per share, for the comparable period in 2013.



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**Year Ended December 31, 2013 Compared to Year Ended December 31, 2012**

License revenues of approximately \$9.1 million and \$2.3 million for the years ended December 31, 2013 and 2012 reflect the amortization of the upfront license fee received from Braeburn in December 2012. Royalty revenues for the years ended December 31, 2013 and 2012 reflect royalties paid on sales of Fanapt, all of which were paid to Deerfield in accordance with our royalty sales agreement. We no longer recognize Fanapt royalty revenues since all of such royalties are paid to third parties. We generated no grant revenue during the year ended December 31, 2013 compared with \$42,000 of NIH grant revenue during the year ended December 31, 2012 relating to our Probuphine program.

Research and development expenses for 2013 were approximately \$8.3 million compared to approximately \$10.6 million in 2012, a decrease of approximately \$2.3 million, or 22%. The decrease in research and development costs was primarily associated with a decrease in external research and development expenses related to completion of the product development program and preparation and review of the NDA for our Probuphine product with the FDA. External research and development expenses include direct expenses such as CRO charges, investigator and review board fees, patient expense reimbursements, expenses for NDA preparation and contract manufacturing expenses.

During 2013, our external research and development expenses relating to our Probuphine product development program were approximately \$3.5 million compared to approximately \$5.4 million for 2012. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this report, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates.

General and administrative expenses for 2013 were approximately \$3.1 million, compared to approximately \$4.9 million in 2012, a decrease of approximately \$1.8 million, or 37%. The decrease in general and administrative expenses was primarily related to decreases in non-cash stock compensation costs of approximately \$1.3 million, employee-related costs of approximately \$0.2 million and consulting and professional fees of approximately \$0.3 million.

Net other income for the year ended December 31, 2013 was approximately \$10.6 million, compared to net other expense of approximately \$6.8 million in the comparable period in 2012. The increase in net other income during the year ended December 31, 2013 was primarily related to approximately \$9.0 million of other income generated by the termination of our royalty repurchase agreement with Deerfield, an approximately \$1.9 million gain resulting from the \$7.5 million settlement of our indebtedness to Deerfield as a result of Deerfield's exercise of all of the Deerfield Warrants, a decrease in interest expense of approximately \$3.3 million related to the Deerfield loans and approximately \$3.5 million related to non-cash gains on changes in the fair value of warrants. This was offset in part by approximately \$0.5 million of other expense related to unamortized transaction fees related to the initial Deerfield debt transaction.

Our net income applicable to common stockholders for the year ended December 31, 2013 was approximately \$9.7 million, or approximately \$0.12 per share, compared to our net loss applicable to common stockholders of approximately \$15.2 million, or approximately \$0.23 per share, for the comparable period in 2012.

**Liquidity and Capital Resources**

We have funded our operations since inception primarily through the sale of our securities and the issuance of debt, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, the sale of

royalty rights and government-sponsored research grants. At June 30, 2014, we had working capital of approximately \$5.0 million compared to working capital of approximately \$6.0 million at December 31, 2013.

Our operating activities used approximately \$2.9 million of cash during the six-months ended June 30, 2014. This consisted primarily of the net loss for the period of approximately \$2.6 million and \$2.0 million related to net changes in other operating assets and liabilities. This was offset in part by non-cash charges of approximately \$0.4 million related to share-based compensation expenses, approximately \$1.1 million related to non-cash losses resulting from changes in the fair value of warrants and approximately \$0.2 million related

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to depreciation and amortization. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Our operating activities used approximately \$9.8 million of cash during the year ended December 31, 2013. This consisted primarily of approximately \$1.9 million related to a non-cash gain on the settlement of long-term debt, approximately \$9.0 million related to a non-cash gain on the termination of our royalty repurchase agreement with Deerfield, approximately \$1.7 million related to net non-cash losses on changes in the fair value of warrants and approximately \$9.1 million related to deferred revenue in connection with the license agreement with Braeburn. This was offset in part by the net income for the period of approximately \$9.7 million, approximately \$0.1 million related to depreciation, and approximately \$0.7 million related to stock-based compensation expenses and approximately \$1.3 million related to net changes in operating assets and liabilities. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Net cash used in investing activities of approximately \$10,000 during the six-months ended June 30, 2014 and \$0.3 million during the year ended December 31, 2013 was primarily related to purchases of equipment.

Net cash used in financing activities of approximately \$37,000 during the six-months ended June 30, 2014 was primarily related to the issuance of restricted stock. Our financing activities provided approximately \$3.8 million during the year ended December 31, 2013. This consisted primarily of approximately \$4.9 million related to sale of common stock, \$1.3 million in proceeds from the exercise of warrants and approximately \$0.1 million in proceeds from the exercise of stock options. This was offset in part by approximately \$2.5 million related to payments on our long-term debt.

In March 2011, we entered into several agreements with entities affiliated with Deerfield pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Pursuant to the terms of a facility agreement, we issued Deerfield 8.5% promissory notes in the aggregate principal amount of \$20.0 million. We paid Deerfield a facility fee of \$0.5 million and issued them the Deerfield Warrants to purchase 6,000,000 shares of our common stock. Under a royalty agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the aggregate royalties on net sales of Fanapt, subsequent to the funding date, constituting a portion of the royalty revenue we receive from Novartis. The agreements with Deerfield also provided us with the option to repurchase the royalty rights for \$40.0 million.

In November 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay them a substantial portion of the remaining future royalties on the sales of Fanapt in exchange for \$5.0 million in cash that was recorded as royalty liability, a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% we previously agreed to pay to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level.

In February 2013, we amended the terms of the Deerfield Warrants to permit payment of the exercise price through the reduction of the outstanding loan. In February and March 2013, Deerfield exercised all of the Deerfield Warrants resulting in a \$7.5 million reduction of our outstanding indebtedness. In April 2013, we made the last \$2.5 million installment payment and our debt obligation to Deerfield was satisfied in full.

In March 2013, we terminated our option to repurchase the royalty rights. As a result, we recognized a gain on the extinguishment of the royalty liability of \$9.0 million, which was recorded in other income, because we are no longer required to account for it as a liability. Additionally, we no longer recognize royalty income related to the Fanapt

royalty payments received from Novartis.

In November 2013, we entered into (i) a stock purchase agreement pursuant to which Braeburn made a \$5.0 million equity investment in our company and (ii) an amendment to the license agreement with Braeburn primarily to modify the amount and timing of the approval and sales milestone payments payable under the license agreement.

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At June 30, 2014, we had cash of approximately \$8.9 million, which we believe is sufficient to fund our planned operations into June 2015.

We are dependent on the proceeds of this offering to advance our current ProNeura development program for Parkinson's disease to later stage clinical studies and to pursue any other research and development programs utilizing the ProNeura platform beyond an initial stage. We will require additional funds, either through payments from Braeburn under the license agreement in the event the Probuphine NDA is ultimately approved or through other financing arrangements, to complete the clinical studies and regulatory approval process necessary to commercialize any additional products we might develop.

In addition, although Braeburn has commenced the clinical study and patient enrollment is underway, under our December 2012 license agreement with Braeburn, as amended, Braeburn currently has the right to terminate the agreement. If Braeburn were to exercise its right to terminate the agreement, we would not have sufficient funds available to us to complete the FDA regulatory process and, in the event of ultimate approval, commercialize Probuphine without raising additional capital. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing in such event, our business and prospects would be materially adversely impacted.

## Contractual Obligations

The following table sets forth the aggregate contractual cash obligations as of December 31, 2013 (in thousands):

Contractual obligations	Payments Due by Period					
	Total	< 1 year	1 - 3 years	3 - 5 years	5 years+	
Operating leases	\$ 525	\$ 208	\$ 317	\$		\$
Total contractual cash obligations	\$ 525	\$ 208	\$ 317	\$		\$

## Recently Issued Accounting Pronouncements

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*, providing guidance on the presentation of unrecognized tax benefits in the financial statements as either a reduction to a deferred tax asset or either a liability to better reflect the manner in which an entity would settle at the reporting date any additional income taxes that would result from the disallowance of a tax position when net operating loss carryforwards, similar tax losses or tax credit carryforwards exist. The amendments in this ASU do not require new recurring disclosures. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The amendments in this ASU should be applied prospectively to all unrecognized tax benefits that exist at the effective date. We do not expect the adoption of the amendments in this ASU will have a significant impact on our financial statements.

## Off-Balance Sheet Arrangements

We have never entered into any off-balance sheet financing arrangements and we have never established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.



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## **BUSINESS**

### **Overview**

We are a specialty pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura®, and focus primarily on innovative treatments for chronic conditions with significant unmet medical needs and meaningful commercial potential.

Probuphine®, our first product candidate to utilize ProNeura, is being developed for the long term maintenance treatment of opioid dependence and is designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. We have licensed the U.S. and Canadian rights to Probuphine to Braeburn. On April 30, 2013, the Psychopharmacologic Drugs Advisory Committee (PDAC) of the FDA voted in favor of approval of Probuphine. However, in April 2013, the FDA issued a CRL to the NDA we submitted the prior year stating that it cannot approve the NDA in its present form and outlining the FDA's request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program for insertion and removal of the implants, as well as recommendations regarding product labeling, REMS and non-clinical safety data. Since receipt of the CRL we have been working with Braeburn, a team of expert clinical and regulatory advisors and the FDA to establish a path forward for Probuphine, which along with other steps includes conducting an additional clinical study in clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patient enrollment in this 180 patient clinical study, which is being funded and managed by Braeburn, began in July 2014 and study completion is anticipated by the middle of 2015 followed by resubmission of the NDA later in the year. Pursuant to our license agreement with Braeburn, as amended to date, we are entitled to receive a \$15 million milestone payment upon FDA approval of the Probuphine NDA and percentage royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. The agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones and entitles us to royalty rates in the low single digit on sales by Braeburn, if any, of other future products in the addiction market.

We believe that our ProNeura technology has the potential to be used in the treatment of other chronic conditions, such as Parkinson's disease (PD), where maintaining stable, around the clock blood levels of a dopamine agonist may benefit the patient and improve medical outcomes. We have commenced initial work on an implant formulation with ropinirole, a dopamine agonist approved for the treatment of PD. We are also currently evaluating drugs and disease settings for opportunities to develop our drug delivery technology for other potential treatment applications in situations where conventional treatment is limited by variability in blood drug levels and poor patient compliance.

## **Our Product Pipeline**

### **Probuphine**

We are developing Probuphine for the maintenance treatment of opioid dependence. Probuphine utilizes ProNeura, our novel, proprietary, long-term drug delivery technology. See ProNeura Continuous Drug Delivery Technology below. Upon subdermal insertion in a patient, Probuphine is designed to release medication continuously and maintain a stable, around the clock blood level of the drug buprenorphine, an approved agent in a daily dosed formulation for the treatment of opioid dependence. If approved, Probuphine is expected to provide six months of medication following a single treatment. Probuphine has been evaluated in the following Phase 3 clinical studies:

Two six-month, double-blind, placebo-controlled safety and efficacy trials; one of which included an open label, active control (Suboxone). In both studies, Probuphine demonstrated superiority to placebo implants, and in the second study, established non-inferiority in comparison to Suboxone;

Two six-month, open-label re-treatment safety trials; and  
A pharmacokinetic (relative bioavailability) safety study.



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The goal of any therapy for an addictive disorder is to reduce the use of the addictive substance over time and to engage the patient in treatment long enough for therapeutic gains to be consolidated. In a clinical study, the effectiveness of a treatment for opioid dependence is primarily evaluated by testing a patient's urine samples for the presence of illicit opioids over the treatment period. In both placebo-controlled Phase 3 studies of Probuphine, every participant was required to provide urine samples three times a week, essentially on alternate days. Any missed sample was considered a positive result (i.e. urine testing positive for illicit opioid). In these studies, the primary effectiveness of the treatment with Probuphine (i.e. the primary endpoint) was established by comparing the negative urine results (i.e. urine testing negative for illicit opioid) between the Probuphine and placebo arms using a statistical technique, specifically the cumulative distribution function of negative urines, which basically performs a comparative analysis on the relative proportions of negative urines between treatment groups over the time period of treatment. The patients in the Probuphine arm showed statistically significant difference in the negative urines as compared to the placebo arm in both studies, i.e. the Probuphine patients had statistically more negative results than the placebo arm, demonstrating that the treatment with Probuphine was successful in reducing their usage of illicit opioids as compared to the treatment with placebo. These favorable results for Probuphine were also confirmed by a significant difference over the placebo arm in other secondary measures such as retention in treatment, withdrawal symptoms and craving for opioids, all of which are monitored by clinicians to see if a treatment is providing benefit to the patients.

Results for the first double-blind, placebo-controlled safety and efficacy study have been published in the Journal of the American Medical Association (JAMA, October 2010) and results of the follow-on randomized three arm study with Probuphine, placebo and sublingual treatment have been published in the journal Addiction (Addiction, September 2013).

Patients who completed the controlled studies were eligible for enrollment in six-month re-treatment studies, which provided data on up to one full year of treatment. The pharmacokinetic safety study has provided important data on the level of buprenorphine in the blood during the treatment period and gives a good profile of the safety of Probuphine. Data from all of these studies was presented at several scientific meetings, including the International Society of Addiction Medicine Annual Meetings in November 2008 and September 2011, the American Society of Addiction Medicine Annual Meetings in May 2009 and 2012, American Society of Addiction Medicine Education Forum in October 2011, and the American College of Neuropharmacology in November 2009 and 2012.

These studies are part of a registration directed program intended to obtain marketing approval of Probuphine for the treatment of opioid dependence in the U.S. and in Europe. We met with the FDA in October 2011 for a pre-NDA meeting and reviewed the clinical development program as well as the chemistry, manufacturing and controls (CMC) aspects of the NDA. Based on this interaction we completed the requirements for an NDA and subsequently prepared and submitted the NDA in October 2012. On April 30, 2013, the FDA issued a complete response letter to our NDA stating that it cannot approve the application in its present form and outlining the FDA's request for additional clinical data demonstrating adequate clinical benefit to patients from this treatment, data from human factors testing of the training program for insertion and removal of the implant, as well as recommendations regarding product labeling, REMS and non-clinical safety data.

Our efforts since receipt of the CRL have focused on working with Braeburn, a team of expert clinical and regulatory advisors and the FDA to establish a path forward for potential resubmission of the NDA with the additional information requested by the FDA. Following a meeting with the FDA on November 19, 2013 and subsequent communications, the FDA has provided guidance on a path forward, which along with other steps includes conducting an additional clinical study. This study is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population is clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8mg or less. Patients will be randomized to receive either four Probuphine implants, or to continue the daily

sublingual buprenorphine therapy. The patients are expected to be treated for six months, and the primary analysis will be a non-inferiority comparison of responders in the two arms. Patient enrollment in this 180 patient clinical study began in July 2014 and study completion is anticipated by the middle of 2015 followed by resubmission of the NDA later in the year.

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Pursuant to the license agreement with Braeburn, as amended to date, we are entitled to receive a \$15 million milestone payment upon FDA approval of the Probuphine NDA and royalty percentages on net sales of Probuphine ranging from the mid-teens to the low twenties. The agreement also provides for up to \$165 million in sales milestones and \$35 million in regulatory milestones and entitles us to royalty rates in the low single digit on sales by Braeburn, if any, of other future products in the addiction market.

### **Market Opportunity**

Opioid dependence, including prescription drug misuse and abuse, is generally recognized to be a major public health and public safety crisis. It is a primary, chronic disease of brain reward, motivation, memory and related neurobiological circuitry that results in an inability to consistently abstain from the opiate, impairment of behavior control, cravings and diminished self-awareness of one's behavioral problems. Addiction involves cycles of relapse and remission and without treatment or engagement in recovery activities is progressive and can result in disability or premature death. In the U.S., daily dose buprenorphine has replaced methadone as the gold standard for treating opioid dependence, in part due to its ceiling effect, improved safety profile and lack of euphoric effect. In 2012, sales of oral buprenorphine (Suboxone®) exceeded \$1.4 billion. We believe that Probuphine, if approved for commercialization, can address issues associated with the oral formulation, including need for daily compliance, fluctuating levels of drug, diversion for illegal sale, and the potential for child access and overdose.

### **ProNeura Continuous Drug Delivery Technology**

Our ProNeura continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released continuously through the process of dissolution. This results in a steady rate of release similar to intravenous administration. We believe that such long-term, linear release characteristics are desirable by avoiding peak and trough level dosing that may pose problems for many disease settings.

The ProNeura technology was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and potentially can provide treatment on an outpatient basis over extended periods of up to 6-12 months. We believe that the benefits of this technology have been demonstrated by the clinical results to date with Probuphine. We believe that this technology has the potential to be useful in the treatment of other diseases.

Accordingly, we have been evaluating opportunities to develop this drug delivery technology for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance and where existing therapeutic compounds have sufficient potency to be effective at low doses. In furtherance of these efforts, during 2012, with the support of a National Institute of Health Small Business Innovation Research grant, we completed a non-clinical study with long-term delivery of ropinirole (Requip™), a dopamine agonist marketed in the U.S. by GlaxoSmithKline for the treatment of Parkinson's disease.

### **Market Opportunity**

Parkinson's disease, or PD, is a disease of the central nervous system characterized by the loss of dopaminergic neurons, which leads to increasing activity in the brain region that influences movement and motor function. According to the Parkinson's Disease Foundation, more than one million people in the U.S. suffer from PD, and this number is projected to double by 2030. Early stage PD patients are treated with drugs designed to replace dopamine in the brain. However, these therapeutics typically lose their benefits after several years of chronic treatment, and trigger serious side effect. About one-third of the treated patients develop motor response fluctuations and/or drug-induced dyskinesias within only 3-5 years of treatment, and these symptoms are present in almost all patients after 10-12

years. Clinical and nonclinical research indicates that these motor side effects arise from the pulsatile dopaminergic stimulation resulting from current oral treatment. Continuous dopaminergic stimulation (CDS) by subcutaneous infusion has been shown to palliate these motor complications, as well as to delay or prevent the onset of dyskinesias.

We believe our ProNeura<sup>TM</sup> drug delivery technology provides a clinically-validated platform to safely and conveniently provide CDS for several months from a single treatment. Further, the subdermal placement of these implants eliminates many of the device-related complications associated with existing treatment modalities.

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The 2012 study, which was conducted using an MPTP Parkinsonian monkey model, demonstrated that a sustained non-fluctuating plasma level of ropinirole could be delivered safely for several months following implantation and could control PD symptoms without triggering dyskinesias in severely lesioned primates. We have begun efforts to optimize an implant formulation of ropinirole and to develop a non-clinical study plan in support of an IND application. We intend to design a proof of concept clinical study with the assistance of scientific advisors and will seek a pre-IND meeting with the FDA in the fourth quarter of this year of the first quarter of 2015. Our goal is to complete the non-clinical studies necessary to enable us to file an IND for the ProNeura ropinirole product in late 2015.

We have also been working with scientific collaborators to evaluate the potential for delivering other therapeutic substances, including peptides, using the ProNeura delivery technology.

### **Fanapt® (iloperidone)**

Fanapt (iloperidone) is an atypical antipsychotic approved by the FDA for the treatment of schizophrenia currently being marketed by Novartis in the U.S. Under a sublicense agreement with Novartis, we are entitled to a royalty of 8-10% of net sales, based on a U.S. patent that we licensed from Sanofi-Aventis. The U.S. patent expires in October 2016 (excluding a six-month pediatric extension). Vanda Pharmaceuticals, Inc. ( Vanda ) owns the development and commercialization rights to the oral and depot formulations of this product for the rest of the world. However, because patent coverage on the compound has now expired in the significant markets outside of the U.S. and no patent term extensions are possible since the product was not approved in these countries prior to patent expiration, we do not expect any royalties on any future sales in such markets.

We have entered into several agreements with Deerfield, which entitle Deerfield to most of the future royalty revenues related to Fanapt in exchange for cash and debt considerations, the proceeds of which have been used to advance the development of Probuphine and for general corporate purposes. We have retained a portion of the royalty revenue from net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will ever receive any revenue from Fanapt. We do not incur any ongoing expenses associated with this product.

### **License Agreements**

In December 2012, we entered into a license agreement (the Agreement ) with Braeburn pursuant to which we granted Braeburn an exclusive right and license to commercialize Probuphine in the United States of America and its territories, including Puerto Rico, and Canada (the Territory ). Under the Agreement, Braeburn made a non-refundable up-front license fee payment of \$15.75 million and agreed to pay us tiered royalties on a percentage of net sales of Probuphine ranging from the mid-teens to the low twenties. Additionally, the Agreement provided for us to receive \$45 million upon FDA approval of the NDA for Probuphine and at such time ownership of the NDA will transfer to Braeburn, as well as up to an additional \$130 million upon the achievement of specified sales milestones and up to \$35 million in regulatory milestones. We will retain all of the rights to Probuphine outside the Territory. Unless earlier terminated, the Agreement will expire on the later of (i) the 15<sup>th</sup> anniversary of the date of product launch in the Territory or (ii) the expiration of the last to expire patent in the Territory covered by the Agreement (the Term ). Either party may terminate the Agreement prior to the expiration of the Term in the event of a material breach by the other party that remains uncured or in the event of the other party's bankruptcy. We may terminate the Agreement if, for reasons other than force majeure, regulatory, safety, manufacturing or product quality issues, Braeburn discontinues commercial sale of the product and fails to resume sales within 30 days following notice or in the event Braeburn or any of its affiliates or sublicensees commences any legal proceeding seeking to challenge or dispute the validity or

ownership of the licensed patents. Braeburn may terminate the Agreement in the event that Braeburn, notwithstanding good faith efforts to do so, is unable to enter into an agreement for the supply of EVA or if such a supply agreement is terminated by Braeburn due to a material breach by the supplier or the supplier fails to provide EVA to Braeburn for a period of at least three months. Braeburn may also terminate the Agreement (i) on a country by country basis upon six months notice following the occurrence of any significant competition in such country, as such term is defined in the Agreement; (ii) immediately upon notice if Braeburn determines in good faith that it is inadvisable to continue commercialization as a result of any actual or perceived safety issues.

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In May 2013, we entered into an amendment to the Agreement (the Amendment ) primarily to modify certain of the termination provisions of the Agreement. The Amendment gives Braeburn the right to terminate the Agreement in the event that (A) after May 28, 2013, based on written or oral communications from or with the FDA, Braeburn reasonably determines either that the FDA will require significant development to be performed before approval of the Probuphine™ NDA can be given, such as, but not limited to, one or more additional controlled clinical studies with a clinical efficacy endpoint, or substantial post-approval commitments that may materially impact the products financial returns or that the FDA will require one or more changes in the proposed label, which change(s) Braeburn reasonably determines will materially reduce the authorized prescribed patient base, or (B) the NDA has not been approved by the FDA on or before June 30, 2014. The Amendment also provides that we will share in legal and consulting expenses in excess of a specified amount prior to approval of the NDA.

In July 2013, we entered into a second amendment to the Agreement (the Second Amendment ) primarily to establish and provide the parameters for a committee comprised of representatives of Titan and Braeburn responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek approval from the FDA of Probuphine® for subdermal use in the maintenance treatment of adult patients with opioid dependence, including development of the strategy for all written and oral communications with the FDA. The Second Amendment also makes Braeburn the primary contact for FDA communications regarding the Probuphine NDA.

In November 2013, we entered into a stock purchase agreement pursuant to which Braeburn made a \$5 million equity investment in our company and a third amendment to the Agreement (the Third Amendment ) primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement. Under the Third Amendment, we are entitled to receive a \$15 million payment upon FDA approval of the NDA, up to \$165 million in sales milestones and \$35 in regulatory milestones. In addition, we are entitled to receive royalties on a percentage of sales in the low single digit by Braeburn, if any, of other continuous delivery treatments for opioid dependence as defined in the Third Amendment and can elect to receive a low single digit royalty on sales by Braeburn, if any, of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine.

In January 1997, we acquired an exclusive worldwide license under U.S. and foreign patents and patent applications relating to the use of iloperidone for the treatment of psychiatric and psychotic disorders and analgesia from Sanofi-Aventis SA ( Sanofi-Aventis ) (formerly Hoechst Marion Roussel, Inc.). The Sanofi-Aventis agreement provides for the payment of royalties on future net sales. In November 1997, we granted a worldwide sublicense, exclusive of Japan, to Novartis under which Novartis continued, at its expense, all further development of iloperidone. In April 2001, that sublicense was extended to include Japan. Under this agreement, Novartis agreed to pay Titan a royalty on future net sales of the product equal to 8% of annual worldwide net sales up to \$200 million and 10% of annual worldwide net sales above \$200 million, in addition to royalty payments owed by us to Sanofi-Aventis. In June 2004, Novartis granted Vanda the worldwide rights to develop and commercialize iloperidone. In October 2009, Vanda and Novartis amended and restated their sub-license agreement whereby Novartis acquired the U.S. and Canadian rights to commercialize Fanapt, the oral formulation of iloperidone approved in the U.S. Novartis also acquired the U.S. and Canadian development and commercialization rights to the depot formulation previously under development by Vanda and retained the right of first negotiation to co-market Fanapt and the depot formulation in the rest of the world. All of our rights and economic interests in iloperidone, including royalties on sales, remained essentially unchanged under these agreements and, as previously stated, we have entered into several agreements with Deerfield, which entitle Deerfield to the future royalty revenues related to Fanapt in exchange for cash and debt considerations.

## Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary



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technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Four patent applications have been filed which incorporate the use of specific compounds with the continuous delivery technology, including three applications related to Probuphine for the potential treatment of opioid addiction and chronic pain. In June 2010, the United States Patent and Trademark Office ( USPTO ) issued a patent covering methods of using Probuphine for the treatment of opiate addiction. Titan is the owner of this patent which claims a method for treating opiate addiction with a subdermally implanted device comprising buprenorphine and EVA, a biocompatible copolymer that releases buprenorphine continuously for extended periods of time. This patent will expire in April 2024. Patents covering use of Probuphine for the treatment of opiate addiction have also issued in Australia, India, Japan, Mexico and New Zealand. Further prosecution of Probuphine applications is currently proceeding at the USPTO and corresponding agencies in Europe, Canada, India and Hong Kong. Patents covering certain dopamine agonist implants have already been issued or allowed in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of the patent application continues in the Israel, India, Japan, and China.

We have received a Notice of Allowance from the USPTO for a patent application covering the sustained release of dopamine agonists utilizing ProNeura.

We have filed additional patent applications for a heterogenous implant designed with some unique properties that may provide benefits to the structural integrity of the implants and potentially enhance drug delivery.

We hold a license from Sanofi-Aventis under certain issued U.S. patents and certain issued foreign patents relating to iloperidone and its methods of use in the treatment of psychiatric disorders, psychotic disorders and analgesia. The term of the U.S. patent that covers certain aspects of our iloperidone product expires in October 2016, excluding a six month extension possible if an approval of pediatric indication is obtained.

## **Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

With respect to Probuphine, Reckitt Benckiser Group, PLC ( Reckitt ) markets globally a sublingual buprenorphine product (tablet and film formulations) for the treatment of opioid dependence. This product (Subutex®, Suboxone®),

which is administered daily, will compete with our six-month implantable product for treating opioid dependence. In September 2012, Reckitt announced the discontinuation of the sublingual tablet formulation of Suboxone in favor of the sublingual film formulation. In addition, during 2013, several generic and a proprietary sublingual tablet formulations of buprenorphine similar to Suboxone and Subutex were approved by the FDA which are expected to compete in the opioid addiction treatment market. Other forms of buprenorphine are also in development by other companies, including intramuscular injections, buccal delivery and intranasally delivered buprenorphine, which also might compete with our product. In 2010, Alkermes, Inc. received FDA approval to market Vivitrol®, a one month depot injection of naltrexone as a maintenance treatment for opioid dependent patients who have successfully achieved abstinence. We are aware of one

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month depot formulations of buprenorphine in early clinical development for the treatment of opioid dependence, but we are not aware of any six-month formulations being developed other than Probuphine.

With respect to our potential ProNeura ropinirole product for Parkinson's disease, there are numerous dopamine agonist treatments currently in use that provide symptom relief from disease related immobility, and the complications associated with long-term levodopa therapy (e.g. dyskinesias, tolerance). Approved products in the U.S. in addition to Requip XL™, which is marketed by GlaxoSmithKline, include Apokyn® (US WorldMeds LLC), Parlodel® (Novartis Pharmaceuticals Inc.), Mirapex ER® (Boehringer Ingelheim Pharmaceuticals Inc.) and Neupro® (UCB Inc.).

## **Manufacturing**

The manufacturing of Probuphine has primarily been conducted at DPT Laboratories, Inc., or DPT, and we have expanded the manufacturing facility at this contract manufacturer to establish commercial scale capability to support the future market launch of Probuphine and ongoing demand following potential approval by the FDA. To date, we have been operating with DPT under an arrangement pursuant to which batches of product needed for validation studies, stability testing or clinical trial purposes are acquired pursuant to purchase orders on a time and product cost basis. We have entered into a commercial manufacturing agreement with DPT that will govern the terms of the production and supply of Probuphine at such time, if ever, as the product is launched commercially. We anticipate that at or prior to such time, such agreement will be assigned to Braeburn as licensee or a replacement agreement entered into between Braeburn and DPT.

To date, we have obtained the supply of buprenorphine from Teva Pharmaceuticals, Inc., or Teva, under an arrangement similar to the one with DPT. We have entered into a commercial supply agreement with Teva; however, we anticipate that at or prior to such time if ever, as the product is launched commercially, such agreement will be assigned to Braeburn as licensee or a replacement agreement entered into between Braeburn and Teva.

## **Sales and Marketing**

We do not currently have and do not intend to establish any sales and marketing capability. As licensee, Braeburn will have sole responsibility for sales and marketing of Probuphine within the United States and Canada. We intend to seek comparable partnering arrangements for Probuphine outside the Territory, as well as for any additional products we may successfully develop based on our ProNeura technology.

## **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

## **FDA Approval Process**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing,

distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of either a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

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Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial.

Once the submission is accepted for filing, the FDA begins an in-depth review. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA may refer applications for novel drug products, or drug products which present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices, or GMP—a quality system regulating manufacturing—is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the

indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with

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specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

### **The Hatch-Waxman Act**

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which the FDA cannot grant effective approval of an ANDA based on the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use; the approval of which was required to be supported by new clinical trials conducted by, or for, the applicant.

### **Section 505(b)(2) New Drug Applications**

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, that enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application. Our NDA for Probuthine was submitted under Section 505(b)(2) and we anticipate that we will pursue this pathway for any additional therapeutic products we may develop based on our ProNeura technology. Section 505(b)(2) permits the

filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of



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the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

### **Advertising and Promotion**

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

### **Adverse Event Reporting and GMP Compliance**

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

### **Pediatric Information**

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity patent or non-patent for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

## **Physician Drug Samples**

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling, and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

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### **Controlled Substances**

Manufacturers of controlled substances, including buprenorphine, are also subject to the licensing, quota, and regulatory requirements of the Controlled Substances Act. Failure to comply with the Controlled Substances Act and the regulations promulgated thereunder could subject companies to loss or suspension of those licenses and to civil or criminal penalties.

### **Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act**

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce; or in return for; purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

### **Foreign Regulatory Issues**

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time required to obtain such approval may be longer or shorter than that required for FDA approval, the requirements for FDA approval are among the most detailed in the world and FDA approval generally takes longer than foreign regulatory approvals.

### **Employees**

As of August 25, 2014, we had 13 full-time employees.

## **Properties**

Our executive offices are located in approximately 9,255 square feet of office space in South San Francisco, California that we occupy under a three-year operating lease expiring in June 2016.

## **Legal Proceedings**

We are currently not a party to any material legal or administrative proceedings and are not aware of any pending or threatened legal or administrative proceedings against us.

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TABLE OF CONTENTS**MANAGEMENT**

Set forth below are the name, age and position and a brief account of the business experience of each of our executive officers and directors:

Name	Age	Title
Marc Rubin	59	Executive Chairman of the Board
Sunil Bhonsle	64	President and Director
Victor J. Bauer	79	Director
Eurelio M. Cavalier	81	Director
M. David MacFarlane	73	Director
Ley Smith	80	Director

**Marc Rubin, M.D.** served as our President and Chief Executive from October 2007 until December 2008 and was re-engaged as our Executive Chairman in May 2009. Until February 2007, Dr. Rubin served as Head of Global Research and Development for Bayer Schering Pharma, as well as a member of the Executive Committee of Bayer Healthcare and the Board of Management of Bayer Schering Pharma. Prior to the merger of Bayer Pharmaceuticals and Schering AG in June 2006, Dr. Rubin was a member of the Executive Board of Schering AG since joining the Company in October 2003, as well as Chairman of Schering Berlin Inc. and President of Berlex Pharmaceuticals, a division of Schering AG. From 1990 until August 2003, Dr. Rubin was employed by GlaxoSmithKline where he held positions of increasing responsibility in global clinical and commercial development overseeing programs in the United States, Europe, Asia and Latin America. From 2001 through 2003, he was Senior Vice President of Global Clinical Pharmacology & Discovery Medicine. Dr. Rubin holds an M.D. from Cornell University Medical College. Dr. Rubin currently serves on the board of directors of Curis Inc. and Galectin Therapeutics. Based on Dr. Rubin's position as the executive chairman, his extensive senior management experience and service on boards of directors in the biotechnology and pharmaceutical industries and his medical background, our Board believes that Dr. Rubin has the appropriate set of skills to serve as a member of the Board.

**Sunil Bhonsle** served as our Executive Vice President and Chief Operating Officer from September 1995 until December 2008 and was re-engaged as our President in May 2009. Mr. Bhonsle served in various positions, including Vice President and General Manager Plasma Supply and Manager Inventory and Technical Planning, at Bayer Corporation from July 1975 until April 1995. Mr. Bhonsle holds an M.B.A. from the University of California at Berkeley and a B.Tech. in chemical engineering from the Indian Institute of Technology. Based on Mr. Bhonsle's position as the president and his substantial experience in the pharmaceutical industry, particularly in the areas of clinical development and manufacturing, our Board believes that Mr. Bhonsle has the appropriate set of skills to serve as a member of the Board.

**Victor J. Bauer, Ph.D.** serves as the President of Concordia Pharmaceuticals, LLC, a biopharmaceutical company he co-founded in 2004. From February 1997 through March 2003, Dr. Bauer was employed by Titan, most recently as our Executive Director of Corporate Development. From April 1996 until its merger into Titan, Dr. Bauer also served as a director and Chairman of Theracell. Since December 1992 Dr. Bauer has been a self-employed consultant to companies in the pharmaceutical and biotechnology industries. Prior to that time, Dr. Bauer was with Hoechst-Roussel Pharmaceuticals Inc., where he served as President from 1988 through 1992. Dr. Bauer holds an SB from MIT and a Ph.D. from the University of Wisconsin, and served as a Research Fellow at Harvard University. Based on Dr. Bauer's extensive management and consulting experience in the biotechnology and pharmaceutical industries, particularly in the areas of research and product development, our Board believes that Dr. Bauer has the appropriate set of skills to serve as a member of the Board.

***Eurelio M. Cavalier*** was employed in various capacities by Eli Lilly & Co. from 1958 until his retirement in 1994, serving as Vice President Sales from 1976 to 1982 and Group Vice President U.S. Pharmaceutical Business Unit from 1982 to 1993. Based on Mr. Cavalier's management experience in the pharmaceutical industry, particularly in the area of sales and marketing, our Board of directors believes that Mr. Cavalier has the appropriate set of skills to serve as a member of the Board.

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**M. David MacFarlane, Ph.D.** served as Vice President and Responsible Head of Regulatory Affairs of Genentech, Inc. from 1989 until his retirement in August 1999. Prior to joining Genentech, Inc., he served in various positions with Glaxo Inc., last as Vice President of Regulatory Affairs. Based on Dr. MacFarlane's management experience in the pharmaceutical industry, particularly in the area of clinical and regulatory affairs, our Board believes that Dr. MacFarlane has the appropriate set of skills to serve as a member of the Board.

**Ley S. Smith** served in various positions with The Upjohn Company and Pharmacia & Upjohn from 1958 until his retirement in November 1997. From 1991 to 1993 he served as Vice Chairman of the Board of The Upjohn Company, and from 1993 to 1995 he was President and Chief Operating Officer of The Upjohn Company. At the time of his retirement, Mr. Smith was Executive Vice President of Pharmacia & Upjohn, and President of Pharmacia & Upjohn's U.S. Pharma Product Center. Based on Mr. Smith's management experience in the pharmaceutical industry, our Board believes that Mr. Smith has the appropriate set of skills to serve as a member of the Board.

# CORPORATE GOVERNANCE

## Independence of Directors

The following members of our Board meet the independence requirements and standards currently established by the NYSE MKT: Victor J. Bauer, Eurelio M. Cavalier, M. David MacFarlane, and Ley S. Smith.

## Board Committees

Our Board has established the following three standing committees: audit committee; compensation committee; and nominating and governance committee, or nominating committee.

The audit committee was formed in compliance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934 (the Exchange Act) and consists of Ley S. Smith, M. David MacFarlane and Victor J. Bauer, each of whom meets the independence requirements and standards currently established by the NYSE MKT and the SEC. In addition, the Board has determined that Mr. Ley S. Smith is an audit committee financial expert and independent as defined under the relevant rules of the SEC and the NYSE MKT. The audit committee assists the Board by overseeing the performance of the independent auditors and the quality and integrity of Titan's internal accounting, auditing and financial reporting practices. The audit committee is responsible for retaining (subject to stockholder ratification) and, as necessary, terminating, the independent auditors, annually reviews the qualifications, performance and independence of the independent auditors and the audit plan, fees and audit results, and pre-approves audit and non-audit services to be performed by the auditors and related fees. During the fiscal year ended December 31, 2013, the audit committee met four times.

The compensation committee makes recommendations to the Board concerning salaries and incentive compensation for our officers, including our Principal Executive Officer, and employees and administers our stock option plans. The compensation committee consists of Eurelio M. Cavalier and Victor J. Bauer, each of whom meets the independence requirements and standards currently established by the NYSE MKT. The compensation committee did not meet as a separate committee or take action by written consent during the fiscal year ended December 31, 2013.

The purpose of the nominating committee is to assist the Board in identifying qualified individuals to become board members, in determining the composition of the Board and in monitoring the process to assess Board effectiveness. The nominating committee consists of Eurelio M. Cavalier, M. David MacFarlane and Ley S. Smith, each of whom

meets the independence requirements and standards currently established by the NYSE MKT. The nominating committee did not meet as a separate committee or take action by written consent during the fiscal year ended December 31, 2013.

The charters for the audit, compensation and nominating committees, which have been adopted by our Board, contain detailed descriptions of the committees' duties and responsibilities and are available in the Investor Relations section of our website at [www.titanpharm.com](http://www.titanpharm.com).

## **Board Leadership Structure**

Currently, our principal executive officer and chairman of the Board positions are held separately by Sunil Bhonsle and Marc Rubin, respectively.



TABLE OF CONTENTS**Role of the Board in Risk Oversight**

Our audit committee is primarily responsible for overseeing our risk management processes on behalf of the full Board. The audit committee receives reports from management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to the full Board, which also considers our risk profile. The audit committee and the full Board focus on the most significant risks we face and our general risk management strategies.

While the Board oversees our risk management, management is responsible for day-to-day risk management processes. Our Board expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our Board leadership structure, which also emphasizes the independence of the Board in its oversight of its business and affairs, supports this approach.

**Board Meetings**

Our business and affairs are managed under the direction of our Board, which is currently composed of **seven** members. The primary responsibilities of the Board are to provide oversight, strategic guidance, counseling and direction to our management. During the fiscal year ended December 31, 2013, the Board met nine times and no director attended fewer than 75% of the meetings of the Board and board committees of which the director was a member.

**Code of Ethics**

We adopted a Code of Business Conduct and Ethics (the Code) in February 2013 that applies to all directors, officers and employees. The Code was filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2012 and is available on our website at [www.titanpharm.com](http://www.titanpharm.com). A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 400 Oyster Point Blvd, Suite 505, South San Francisco, California 94080.

**EXECUTIVE COMPENSATION**

The following table shows information concerning the annual compensation for services provided to us by our Chief Executive Officer, our Chief Financial Officer and our other executive officers for the periods set forth.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Options <sup>(1)</sup> Awards (\$)	Stock Awards <sup>(1)</sup> (\$)	All Other Compensation (\$)	Total Compensation (\$)
Marc Rubin, M.D. Executive Chairman	2013	\$210,000	\$	\$	\$	\$	\$ 210,000
	2012	\$210,000	53,000	273,450			\$ 536,450
Sunil Bhonsle President and Chief Financial Officer	2013	300,000					300,000
	2012	300,000	75,000	328,140			703,140

(1) Amounts shown represent the grant date fair value computed in accordance with FASB ASC 718. For a description of the material terms of employment agreements with our current and former named executive officers, see Employment Agreements.

There were no grants of plan based awards to any named executive officer during the year ended December 31, 2013.

## Employee Benefits Plans

The principal purpose of our stock incentive plans is to attract, motivate, reward and retain selected employees, consultants and directors through the granting of stock-based compensation awards. The stock option plans provides for a variety of awards, including non-qualified stock options, incentive stock options (within the meaning of Section 422 of the Code), stock appreciation rights, restricted stock awards, performance-based awards and other stock-based awards.

TABLE OF CONTENTS**2002 Stock Incentive Plan**

In July 2002, we adopted the 2002 Stock Incentive Plan, or the 2002 Plan. Under the 2002 Plan, as amended, a total of approximately 7.4 million shares of our common stock were authorized for issuance to employees, officers, directors, consultants, and advisers. The 2002 Plan expired by its terms in July 2012. On the Record Date, options to purchase an aggregate of 4,170,153 shares of our common stock were outstanding under the 2002 Plan.

**2001 Stock Option Plan**

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan, or the 2001 NQ Plan, pursuant to which 1,750,000 shares of common stock were authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. The 2001 NQ Plan expired by its terms in August 2011. On the Record Date, options to purchase an aggregate of 1,199,500 shares of our common stock were outstanding under the 2001 NQ Plan.

**2014 Incentive Plan**

On February 11, 2014, our Board adopted the 2014 Incentive Plan, or the 2014 Plan, pursuant to which 2,500,000 shares of our common stock were authorized for issuance to employees, directors, officers, consultants and advisers. See Proposal No. 2 Approval of the Titan Pharmaceuticals, Inc. 2014 Incentive Plan.

## OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table summarizes the number of securities underlying outstanding plan awards for each named executive officer as of December 31, 2013.

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
Marc Rubin, M.D.	437,500		\$ 2.40	10/01/2017
	2,500		1.52	5/30/2018
	5,000		1.52	5/30/2018
	615,000		0.79	5/17/2019
	100,000		0.79	5/17/2019
	5,000		0.79	5/17/2019
	10,000		0.79	5/17/2019
	285,000		0.79	5/17/2019
	150,000		1.40	4/15/2021
	250,000		1.15	1/3/2022

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Sunil Bhonsle	60,000	3.69	2/9/2014
	70,000	2.62	2/7/2015
	80,137	1.40	1/3/2016
	11,250	2.35	8/29/2016
	76,666	3.13	1/3/2017
	5,000	1.52	5/30/2018
	310,000	0.79	5/17/2019
	100,000	0.79	5/17/2019
	10,000	0.79	5/17/2019
	390,000	0.79	5/17/2019
	200,000	1.40	4/15/2021
	300,000	1.15	1/3/2022

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The following table summarizes the option exercises by our named executive officers during 2013.

Name	Number of Shares Acquired on Exercise	Value Realized on Exercise <sup>(1)</sup>
Sunil Bhonsle	50,000	19,500

<sup>(1)</sup> Represents the amounts realized based on the difference between the market price of our common stock on the date of exercise and the exercise price.

**Pension Benefits**

We do not sponsor any qualified or non-qualified defined benefit plans.

**Nonqualified Deferred Compensation**

We do not maintain any non-qualified defined contribution or deferred compensation plans. The compensation committee, which is comprised solely of outside directors as defined for purposes of Section 162(m) of the Code, may elect to provide our officers and other employees with non-qualified defined contribution or deferred compensation benefits if the compensation committee determines that doing so is in our best interests. We sponsor a tax qualified defined contribution 401(k) plan in which Dr. Rubin and Mr. Bhonsle participated.

**CERTAIN RELATIONSHIPS AND RELATED  
TRANSACTIONS**

There were no related party transactions in 2013 and, as of the date of this proxy statement, none have been undertaken in 2014.

TABLE OF CONTENTS**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth as of August 25, 2014, the number of shares of our common stock beneficially owned by (i) each person who is known by us to be the beneficial owner of more than five percent of our common stock; (ii) each director and director nominee; (iii) each of the named executive officers in the Summary Compensation Table; and (iv) all directors and executive officers as a group. As of August 25, 2014, we had 88,997,533 shares of common stock issued and outstanding.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission (the SEC ) and generally includes voting or investment power with respect to securities. Unless otherwise indicated, the stockholders listed in the table have sole voting and investment power with respect to the shares indicated.

Name and Address of Beneficial Owner <sup>(1)</sup>	Shares Beneficially Owned <sup>(2)</sup>	Percent of Shares Beneficially Owned
Victor J. Bauer, Ph.D.	296,144 <sup>(3)</sup>	*
Sunil Bhonsle	1,994,310 <sup>(4)</sup>	2.2 %
Eurelio M. Cavalier	422,500 <sup>(5)</sup>	*
M. David MacFarlane, Ph.D.	317,500 <sup>(6)</sup>	*
Marc Rubin, M.D.	2,467,200 <sup>(7)</sup>	2.7*
Ley S. Smith	352,500 <sup>(8)</sup>	*
Braeburn Pharmaceuticals BVBA SPRL	9,650,000 <sup>(9)</sup>	10.8 %
Robert E. Mead	4,695,044 <sup>(10)</sup>	5.3 %
All executive officers and directors as a group (6) persons	5,850,154	6.4 %

\* Less than one percent.

(1) Unless otherwise indicated, the address of such individual is c/o Titan Pharmaceuticals, Inc., 400 Oyster Point Boulevard, Suite 505, South San Francisco, California 94080.

In computing the number of shares beneficially owned by a person and the percentage ownership of a person, shares of our common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of March 24, 2014 are deemed outstanding. Such shares, however, are not deemed outstanding for purposes of computing the percentage ownership of each other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

(3) Includes 260,000 shares issuable upon exercise of outstanding options.

(4) Includes (i) 1,553,053 shares issuable upon exercise of outstanding options and (ii) 300,757 shares held in a family trust for which he serves as trustee.

(5) Includes 240,000 shares issuable upon exercise of outstanding options.

(6) Includes 195,000 shares issuable upon exercise of outstanding options.

(7) Includes 1,860,000 shares issuable upon exercise of outstanding options.

(8) Includes 240,000 shares issuable upon exercise of outstanding options.

(9) Derived from a Schedule 13D filed by Braeburn, Apple Tree Consolidated BVBA Sprl ( ATC ), Apple Tree Investments S.a.r.l ( ATI ), Apple Tree Partners IV, L.P. ( ATP IV ), ATP III GP, Ltd. ( ATP GP ) and Seth L.

Harrison ( Harrison ). ATP GP is the sole general partner of ATP IV. Harrison is the sole owner and director of ATP GP. As the sole owner of Braeburn, ATC may be deemed to own beneficially such shares. As the sole owner of ATC, ATI may be deemed to own beneficially such shares. As the sole owner of ATI, ATP IV may be deemed to own beneficially such shares. As the sole general partner of ATP IV, ATP GP may be deemed to own beneficially such shares. As the sole owner and director of ATP GP, Harrison may be deemed to own beneficially such shares. Each of the foregoing persons except Braeburn, disclaims beneficial ownership of such shares except to the extent of their pecuniary interest therein, if any. The address of the principal business office of Braeburn is Brugmannlaan 147, 1190 Vorst, Belgium.

(10) Derived from a Schedule 13G filed by Mr. Mead. The address of Mr. Mead's principal business office is 3653 Maplewood Ave., Dallas, TX 75205.

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## DESCRIPTION OF CAPITAL STOCK

*The following is a summary of all material characteristics of our capital stock as set forth in our certificate of incorporation and bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our articles of incorporation and bylaws, all of which are incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and to the provisions of the Delaware General Corporation Law.*

### Common Stock

Our charter authorizes the issuance of up to 125,000,000 shares of common stock, par value \$0.001 per share. As of August 25, 2014, there were 88,997,533 shares of common stock outstanding, as well as 12,479,445 shares of common stock subject to outstanding options and warrants and unvested restricted stock awards. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that are outstanding or that we may designate and issue in the future. All of our outstanding shares of common stock are fully paid and nonassessable.

### Preferred Stock

We are authorized to issue 5,000,000 shares of preferred stock, par value \$0.0001 per share, none of which are currently outstanding. Our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. However, the underwriting agreement prohibits us, prior to a business combination, from issuing preferred stock which participates in any manner in the proceeds of the trust account, or which votes as a class with the common stock on a business combination. We may issue some or all of the preferred stock to effect a business combination. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

### Options

As of August 25, 2014, we had outstanding options to purchase an aggregate of 6,670,053 shares of our common stock, with a weighted average exercise price of \$1.25.



## Restricted Stock Awards

As of August 25, 2014, we had outstanding unvested restricted stock awards representing 358,500 shares of our common stock.

## Warrants

On April 9, 2012, in connection with subscription agreements with certain institutional investors for the purchase and sale of 6,517,648 shares of our common stock, we issued (i) six-year warrants ( Series A Warrants ) to purchase 6,517,648 shares of common stock at an exercise price of \$1.15 per share and (ii) six-month warrants ( Series B Warrants ) to purchase 6,517,648 shares of common stock at an exercise price of \$0.85 per share. During the year ended December 31, 2012, Series B Warrants to purchase 5,761,765 shares of common stock were exercised at a price of \$0.85 per share. The remaining Series B

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Warrants to purchase 755,883 shares of common stock expired in October 2012. During the year ended December 31, 2013, Series A Warrants to purchase 1,109,010 shares of common stock were exercised resulting in gross proceeds of approximately \$1,275,000. The remaining Series A Warrants to purchase 5,408,638 shares of common stock will expire in April 2018.

We also have outstanding warrants to purchase 42,254 shares of common stock at an exercise price of \$2.13 held by a former lender which expire in December 2014.

## **Our Transfer Agent**

The transfer agent for our common stock is Continental Stock Transfer & Trust Company, New York, New York.

## **Delaware Anti-Takeover Law**

We will be subject to the provisions of Section 203 of the DGCL regulating corporate takeovers upon consummation of this offering. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a business combination with:

a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an interested stockholder );  
an affiliate of an interested stockholder; or

an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A business combination includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

our board of directors approves the transaction that made the stockholder an interested stockholder, prior to the date of the transaction;

after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or

on or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

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## **DESCRIPTION OF SECURITIES WE ARE OFFERING**

We are offering units, each unit consisting of one share of our common stock and [\*] of one Class A Warrant, each to purchase one share of our common stock.

The units will not be issued or certificated. The shares of common stock and the Class A Warrants that we are issuing are immediately separable and will be issued separately. We are also registering the shares of common stock issuable from time to time upon exercise of the Class A Warrants offered hereby.

### **Common Stock**

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described under the caption **Description of Capital Stock** in this prospectus.

### **Class A Warrants**

The following summary of certain terms and provisions of Class A Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the Class A Warrant, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions of the form of Class A Warrant for a complete description of the terms and conditions of the Class A Warrants.

### **Duration and Exercise Price**

The Class A Warrants offered hereby will entitle the holders thereof to purchase an aggregate of [\*] shares of our common stock at an initial exercise price per share of common stock of [\*]. The Class A Warrants will be immediately exercisable and will expire on the [\*] anniversary of the date of issuance. The Class A Warrants will be issued separately from the common stock included in the units, and may be transferred separately immediately thereafter. Class A Warrants will be issued in certificated form only.

### **Exercisability**

The Class A Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% of the outstanding common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Class A Warrants.

### **Cashless Exercise**

If, at the time a holder exercises its Class A Warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the Class A Warrant to the

holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Class A Warrant.

## **Fundamental Transactions**

In the event of any fundamental transaction, as described in the Class A Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a Class A Warrant, the holder will have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the Class A Warrant is exercisable immediately prior to such event.

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**Transferability**

Subject to applicable laws and the restriction on transfer set forth in the Class A Warrant, the Class A Warrant may be transferred at the option of the holder upon surrender of the Class A Warrant to us together with the appropriate instruments of transfer.

**Exchange Listing**

We do not intend to list the Class A Warrants on any securities exchange or other trading market.

**Right as a Shareholder**

Except as otherwise provided in the Class A Warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the Class A Warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Class A Warrants.

**Waivers and Amendments**

Subject to certain exceptions, any term of the Class A Warrants may be amended or waived with our written consent and the written consent of the holders of at least a majority of the then-outstanding Class A Warrants.

TABLE OF CONTENTS**UNDERWRITING**

We have entered into an underwriting agreement with Roth Capital Partners, LLC with respect to the units subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase, the number of units provided below opposite its name.

Underwriter	Number of Units
Roth Capital Partners, LLC	
Total	

The underwriter is offering the units subject to its acceptance of the units from us and subject to prior sale. The underwriting agreement provides that the obligation of the underwriter to pay for and accept delivery of the units offered by this prospectus are subject to the approval of certain legal matters by its counsel and to certain other conditions. The underwriter is obligated to take and pay for all of the units if any such units are taken.

**Discounts, Commissions and Expenses**

The underwriter has advised us that it proposes to offer the units to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$[\*] per unit. The underwriter may allow, and certain dealers may reallocate, a discount from the concession not in excess of \$[\*] per unit to certain brokers and dealers. After this offering the initial public offering price, concession and reallocation to dealers may be changed by the underwriter. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The units are offered by the underwriter as stated herein, subject to receipt and acceptance by it and subject to its right to reject any order in whole or in part. The underwriter has informed us that it does not intend to confirm sales to any accounts over which it exercises discretionary authority.

The following table shows the underwriting discounts and commissions payable to the underwriter by us in connection with this offering:

	Per unit <sup>(1)</sup>	Total
Public offering price	\$	\$
Underwriting discount	\$	\$

(1) Does not include the warrants to purchase shares of common stock equal to 3.0% of the number of shares included in the units sold in the offering to be issued to the underwriter at the closing.

We estimate that expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$[\*]. We have agreed to reimburse the underwriter for certain out-of-pocket expenses provided that expenses exceeding \$75,000 will require our prior approvals, such approval not to be unreasonably withheld.

**Underwriter s Warrants**

We have also agreed to issue to the underwriter warrants to purchase a number of our shares of common stock equal to an aggregate of 3.0% of the shares of common stock included in the units sold in this offering. The underwriter s

warrants will have an exercise price equal to the public offering price of the units set forth on the cover of this prospectus and may be exercised on a cashless basis. The underwriter's warrants are not redeemable by us. This prospectus also covers the sale of the underwriter's warrants and the shares of common stock issuable upon the exercise of the underwriter's warrants. Except as described above or as summarized below, the underwriter's warrants will be in substantially the same form as the Class A Warrants included in the units. The underwriter's warrants and the underlying shares of common stock have been deemed compensation by the Financial Institutions Regulatory Authority, Inc., or FINRA, and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the underwriter's warrants nor any shares of our common stock issued upon exercise of the underwriter's warrants may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a

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period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the underwriter's warrants are being issued, except the transfer of any security:

by operation of law or by reason of reorganization of our company;  
to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period;  
if the aggregate amount of our securities held by either an underwriter or a related person do not exceed 1% of the securities being offered;  
that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or  
the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.  
In addition, in accordance with FINRA Rule 5110(f)(2)(G), the underwriter's warrants may not contain certain terms.

## **Indemnification**

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act of 1933.

## **Lock-up Agreements**

We, our officers, directors and certain of our shareholders have agreed, subject to limited exceptions, for a period of 90 days after the date of the underwriting agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of the underwriter. This 90-day period may be extended if (1) during the last 17 days of the 90-day period, we issue an earnings release or material news or a material event regarding us occurs or (2) prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period, then the period of such extension will be 18 days, beginning on the issuance of the earnings release or the occurrence of the material news or material event. If after any announcement described in clause (2) of the preceding sentence, we announce that we will not release earnings results during the 16-day period, the lock-up period shall expire the later of the expiration of the 90-day period and the end of any extension of such period made pursuant to clause (1) of the preceding sentence. The underwriter may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

## **Price Stabilization, Short Positions and Penalty Bids**

The underwriter has advised us that it does not intend to conduct any stabilization or over-allotment activities in connection with this offering.



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## **Electronic Distribution**

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriter, or by its affiliates. Other than this prospectus in electronic format, the information on the underwriter's website and any information contained in any other website maintained by the underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

## **Other**

From time to time, the underwriter and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services it has received and, may in the future receive, customary fees. Except for services provided in connection with this offering, the underwriter has not provided any investment banking or other financial services during the 180-day period preceding the date of this prospectus and we do not expect to retain the underwriter to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

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## NOTICE TO INVESTORS

### Notice to Investors in the United Kingdom

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ) an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any such securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) by an underwriter to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of these securities shall result in a requirement for the publication by the issuer or the underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any such securities to be offered so as to enable an investor to decide to purchase any such securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

The underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the FSMA)) received by it in connection with the issue or sale of any of the securities in circumstances in which section 21(1) of the FSMA does not apply to the issuer; and
- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

### European Economic Area

In particular, this document does not constitute an approved prospectus in accordance with European Commission Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made in that Relevant Member State prior to the publication of a prospectus in relation to such securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and

notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of securities to the public in that Relevant Member State at any time:

to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

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to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in the last annual or consolidated accounts; or

in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of securities to the public in relation to any of the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the units offered hereby are securities.

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## **LEGAL MATTERS**

The validity of the shares of our common stock offered hereby has been passed upon for us by Loeb & Loeb LLP, New York, New York. Lowenstein Sandler LLP, New York, New York, is acting as counsel for the underwriter in this offering.

## **EXPERTS**

The financial statements as of and for the years ended December 31, 2013 and 2012 have been incorporated by reference in this prospectus in reliance on the report of OUM & Co. LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## **INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

This prospectus incorporates by reference important business and financial information that we file with the SEC and that we are not including in or delivering with this prospectus. As the SEC allows, incorporated documents are considered part of this prospectus, and we can disclose important information to you by referring you to those documents. We incorporate by reference the documents listed below:

The financial statements of our company as of and for the years ended December 31, 2013 and 2012 and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 31, 2014; and

The financial statements of our company as of and for the six months ended June 30, 2014 and 2013 and the notes thereto included in our Quarterly Report on Form 10-Q for the period ended June 30, 2014 filed with the SEC on August 13, 2014.

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## WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC in connection with this offering. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy the registration statement and any other documents we have filed at the Securities and Exchange Commission's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information on its Public Reference Room. Our SEC filings are also available to the public at the SEC's Internet site at <http://www.sec.gov>. Our Internet website address is <http://www.titanpharm.com>. Information contained on the website does not constitute part of this registration statement.

This prospectus is part of the registration statement and does not contain all of the information included in the registration statement. Whenever a reference is made in this prospectus to any of our contracts or other documents, the reference may not be complete and, for a copy of the contract or document, you should refer to the exhibits that are a part of the registration statement.

You may request a copy of these filings, at no cost, by contacting us at:

Titan Pharmaceuticals, Inc.  
400 Oyster Point Boulevard, Suite 550  
South San Francisco, CA  
(650) 989-2268  
Attention: Brian Crowley

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**Units**

**Each Unit Consisting of One Share of Common Stock**

**and**

**[\*] of a Class A Warrant, Each to Purchase One Share  
of Common Stock**

**TITAN PHARMACEUTICALS, INC.**

**Common Stock**

**PROSPECTUS**

, 2014

**Roth Capital Partners**

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the various expenses, all of which will be borne by the registrant, in connection with the sale and distribution of the securities being registered, other than the underwriting discounts and commissions. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	\$ 2,365
FINRA fees	\$ 3,254
Printing and engraving expenses	\$
Accounting fees and expenses	\$
Legal fees and expenses	\$ 75,000
Miscellaneous	\$
Total	\$

**Item 14. Indemnification of Directors and Officers.**

**Amended and Restated Bylaws**

Pursuant to our bylaws, our directors and officers will be indemnified to the fullest extent allowed under the laws of the State of Delaware for their actions in their capacity as our directors and officers.

We must indemnify any person made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative ( Proceeding ) by reason of the fact that he is or was a director, against judgments, penalties, fines, settlements and reasonable expenses (including attorney s fees) ( Expenses ) actually and reasonably incurred by him in connection with such Proceeding if: (a) he conducted himself in good faith, and: (i) in the case of conduct in his own official capacity with us, he reasonably believed his conduct to be in our best interests, or (ii) in all other cases, he reasonably believes his conduct to be at least not opposed to our best interests; and (b) in the case of any criminal Proceeding, he had no reasonable cause to believe his conduct was unlawful.

We must indemnify any person made a party to any Proceeding by or in the right of us, by reason of the fact that he is or was a director, against reasonable expenses actually incurred by him in connection with such proceeding if he conducted himself in good faith, and: (a) in the case of conduct in his official capacity with us, he reasonably believed his conduct to be in our best interests; or (b) in all other cases, he reasonably believed his conduct to be at least not opposed to our best interests; provided that no such indemnification may be made in respect of any proceeding in which such person shall have been adjudged to be liable to us.

No indemnification will be made by unless authorized in the specific case after a determination that indemnification of the director is permissible in the circumstances because he has met the applicable standard of conduct.

Reasonable expenses incurred by a director who is party to a proceeding may be paid or reimbursed by us in advance of the final disposition of such Proceeding in certain cases.

We have the power to purchase and maintain insurance on behalf of any person who is or was our director, officer, employee, or agent or is or was serving at our request as an officer, employee or agent of another corporation, partnership, joint venture, trust, other enterprise, or employee benefit plan against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such, whether or not we would have the power to indemnify him against such liability under the provisions of the amended and restated bylaws.

## **Delaware Law**

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal,

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administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

## **Indemnification Agreements**

As permitted by the Delaware General Corporation Law, we have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit

or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of us or any of our affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding,

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had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy covering its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

## **Item 15. Recent Sales of Unregistered Securities.**

The information below lists all of the securities sold by us during the past three years which were not registered under the Securities Act:

1. In November 2013, we sold 6,250,000 shares of common stock to Braeburn Pharmaceuticals Sprl for an aggregate purchase price of \$5.0 million.
2. In September 2012, we sold 3,400,000 shares to Braeburn Pharmaceuticals Sprl for an aggregate purchase price of \$4.25 million.

## **Item 16. Exhibits and Financial Statement Schedules.**

(a) The following exhibits are filed as part of this Registration Statement:

- |      |   |
|------|---|
| 1.1* | Form of Underwriting Agreement  |
| 3.1  | Amended and Restated Certificate of Incorporation of the Registrant, as amended <sup>(9)</sup>  |
| 3.2  | By-laws of the Registrant <sup>(1)</sup>  |
| 3.3  | Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. <sup>(15)</sup>  |
| 4.1  | Registration Rights Agreement dated as of December 17, 2007 <sup>(2)</sup>  |
| 4.2  | Registration Rights Agreement dated as of December 8, 2009 <sup>(9)</sup>   |
| 4.3  | Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation <sup>(9)</sup>  |
| 4.4  | Form of Warrant <sup>(13)</sup>   |
| 4.5  | Registration Rights Agreement, dated as of March 15, 2011 <sup>(13)</sup>   |
| 4.6  | Form of Series A Warrant <sup>(18)</sup>  |
| 4.7* | Form of Class A Warrant   |
| 5.1* | Opinion of Loeb & Loeb LLP  |
| 10.1 | 1998 Stock Option Plan <sup>(3)</sup>   |
| 10.2 | 2001 Non-Qualified Employee Stock Option Plan <sup>(4)</sup>  |
| 10.3 | 2002 Stock Option Plan <sup>(5)</sup>   |
| 10.4 | Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, |

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2012<sup>(9),(16),(19)</sup>

10.5 Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012<sup>(9),(16),(19)</sup>

10.6 Lease for the Registrant's facilities, amended as of October 1, 2004<sup>(9)</sup>

10.7 Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009<sup>(9)</sup>

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10.8**	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 <sup>(7)</sup>
10.9**	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 <sup>(8)</sup>
10.10	Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated December 18, 2009 <sup>(9)</sup>
10.11	Stock Purchase Agreement between the Registrant and certain investors dated December 8, 2009 <sup>(9)</sup>
10.12	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Marc Rubin <sup>(10)</sup>
10.13	Amendment to Employment Agreement dated June 15, 2010 between the Registrant and Sunil Bhonsle <sup>(10)</sup>
10.14	Amendment to lease for Registrant's facilities dated June 15, 2010 <sup>(1)</sup>
10.15	Amended and Restated Loan and Security Agreement between the Registrant and Oxford Finance Corporation dated September 27, 2010 <sup>(12)</sup>
10.16	Facility Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited, as amended on February 6, 2013 <sup>(13)(26)</sup>
10.17	Security Agreement, dated as of March 15, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>(13)</sup>
10.18	Royalty Purchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>(14)</sup>
10.19	Amended and Restated Royalty Agreement, dated November 14, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>(14)</sup>
10.20	Amended and Restated Royalty Repurchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., and Horizon Sante TTNP SARL <sup>(14)</sup>
10.21	Cash Management Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>(14)</sup>
10.22	Paying Agent Agreement, dated November 14, 2011, by and among the Company, Deerfield Management Company, L.P. and U.S. Bank National Association <sup>(14)</sup>
10.23	Agreement, dated as of November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P., and Deerfield Special Situations Fund International Limited <sup>(14)</sup>
10.24	Form of Subscription Agreement dated April 9, 2012 <sup>(18)</sup>
10.25**	License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl, dated December 14, 2012 <sup>(20)</sup>
10.26	Amendment dated May 28, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>(21)</sup>
10.27	Second Amendment dated July 2, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>(22)</sup>

10.28 Third Amendment dated November 12, 2013 to License Agreement by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl<sup>(23)</sup>

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10.29	Stock Purchase Agreement dated November 12, 2013 by and between Titan Pharmaceuticals, Inc. and Braeburn Pharmaceuticals Sprl <sup>(23)</sup>
10.30	2014 Incentive Plan <sup>(24)</sup>
14.1	Code of Business Conduct and Ethics <sup>(25)</sup>
23.1	Consent of OUM & Co., LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Loeb & Loeb LLP (included in Exhibit 5.1)
24.1#	Power of Attorney (included in signature page to this Registration Statement)
31.1	Certification of the Principal Executive and Financial Officer pursuant to Rule 13(a)-14(a) of the Securities Exchange Act of 1934
32.1	Certification of the Principal Executive and Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS***	XBRL Instance Document <sup>(25)</sup>
101.SCH***	XBRL Taxonomy Extension Schema Document <sup>(25)</sup>
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document <sup>(25)</sup>
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document <sup>(25)</sup>
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document <sup>(25)</sup>
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document <sup>(25)</sup>

- (1) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 33-99386).
- (2) Incorporated by reference from the Registrant's Current Report on Form 8-K dated December 27, 2007.
- (3) Incorporated by reference from the Registrant's definitive Proxy Statement filed on July 28, 2000.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
- (6) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005.
- (7) Incorporated by reference from the Registrant's Annual Report on Form 10-KSB for the year ended December 31, 1996.
- (8) Incorporated by reference from the Registrant's Registration Statement on Form S-3 (File No. 333-42367).
- (9) Incorporated by reference from the Registrant's Registration Statement on Form 10.
- (10) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003.
- (11) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended June 30, 2010.
- (12) Incorporated by reference from the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2010.
- (13) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on March 18, 2011.
- (14) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on November 17, 2011.
- (15) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on December 21, 2011.
- (16) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 4, 2012.
- (17) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011.

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- (18) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on April 10, 2013.
- (19) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on January 2, 2013.
- (20) Incorporated by reference from the Registrant's Current Report on Form 8-K/A filed on February 28, 2013.
- (21) Incorporated by reference from the Registrant's Current Report on Form 8-K dated May 29, 2013.
- (22) Incorporated by reference from the Registrant's Current Report on Form 8-K dated July 5, 2013.
- (23) Incorporated by reference from the Registrant's Current Report on Form 8-K dated November 13, 2013.
- (24) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2013.
- (25) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012.
- (26) Incorporated by reference from the Registrant's Current Report on Form 8-K filed on February 7, 2014.

# Filed herewith.

\* To be filed by amendment.

\*\* Confidential treatment has been granted with respect to portions of this exhibit.

\*\*\* Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101.1 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which

ii. was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That for the purpose of determining any liability under the Securities Act of 1933 in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following

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communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser
- The undersigned hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement or amendment thereto to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Francisco, State of California, on August 29, 2014.

**TITAN PHARMACEUTICALS, INC.**

/s/ Sunil Bhonsle

By:

Name: Sunil Bhonsle

Title: President

**POWER OF ATTORNEY**

KNOWN ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Sunil Bhonsle and Marc Rubin his true and lawful attorney-in-fact, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments (including post-effective amendments) to this registration statement (and to any registration statement filed pursuant to Rule 462 under the Securities Act of 1933, as amended), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Marc Rubin	Executive Chairman of the Board of Directors	August 29, 2014
Marc Rubin, M.D. /s/ Sunil Bhonsle	President and Director (principal executive and principal financial officer)	August 29, 2014
Sunil Bhonsle, Ph.D. /s/ Brian Crowley	Vice President Finance (principal accounting officer)	August 29, 2014
Brian Crowley /s/ Victor J. Bauer	Director	August 29, 2014
Victor J. Bauer /s/ Eurelio Cavalier	Director	August 29, 2014
Eurelio Cavalier, M.D. /s/ M. David MacFarlane	Director	August 29, 2014
M. David MacFarlane		

/s/ Ley Smith

Director

August 29, 2014

Ley Smith

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